

**“ EFFECTS OF INTRALESIONAL TRIAMCINALONE
INJECTION FOLLOWING INTERNAL URETHROTOMY IN
TREATMENT OF STRICTURE URETHRA- A PROSPECTIVE
ANALYTICAL EXPERIMENTAL STUDY”**

**Dissertation submitted to
THE TAMILNADU DR. M.G.R.MEDICAL UNIVERSITY
in partial fulfilment for the award of the degree of**

**MASTER OF CHIRURGIE
IN
UROLOGY
BRANCH IV**



**GOVT.STANLEY MEDICAL COLLEGE AND HOSPITAL
CHENNAI- 600 001**

AUGUST 2014

CERTIFICATE

This is to certify that dissertation titled **“EFFECTS OF INTRALESIONAL TRIAMCINALONE INJECTION FOLLOWING INTERNAL URETHROTOMY FOR TREATMENT OF STRICTURE URETHRA” - A PROSPECTIVE ANALYTICAL EXPERIMENTAL STUDY**” of **Dr.E.P.RAJARAJAN** in partial fulfillment of the requirements for M.Ch. Branch -IV (urology) Examination of the Tamil Nadu Dr. M.G.R Medical University to be held in August 2014. The period of study was from January 2013 -February 2014.

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DECLARATION

I ,**Dr.E.P.RAJARAJAN** solemnly declared that dissertation titled“**EFFECTS OF INTRALESIONAL TRIAMCINALONE INJECTION FOLLOWING INTERNAL URETHROTOMY FOR TREATMENT OF STRICTURE URETHRA - PROSPECTIVE ANALYTICAL EXPERIMENTAL STUDY**”is a bonafide work done by me at Govt.Stanley Medical College & Hospital during January 2013 to February 2014 under the guidance and supervision of Unit Chief **Prof.Dr.V.Selvaraj, M.S., M.ch. (Urology)** ,Professor and Head Of The Department.

The dissertation is submitted to Tamil Nadu, Dr. M.G.R university, towards partial fulfillment of requirement for the award of M.Ch. Degree(Branch-IV) in urology three years course.

Place: Chennai

Date:

Dr.E.P.Rajarajan

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INTRODUCTION

INTRODUCTION

stricture disease of urethra is always a challenge for almost all practicing urologists. Treatment options available such as dilatation, DVIU, placement of stent, single or various stages of urethroplasty.

Management by endoscopy is routinely done first for short bulbar urethral strictures before other modality of treatment. The reported success rate of single DVIU is **20 to 60 %**. DVIU doesn't produce epithelial approximation but it separates scarred epithelium so, wound heals by secondary intention. If wound contraction takes place before full epithelialisation, it significantly narrows lumen and results in recurrence.

Injection of steroid triamcinolone intralesionally following internal urethrotomy, decreases formation of scar by enhancing endogenous production of collagenase and obviates scar formation. In our study we analysed the outcome of injection of steroid (triamcinolone) & urethral stricture recurrence after DVIU. We analysed time duration between VIU and urethral stricture disease recurrence.

REVIEW of LITERATURE

REVIEW OF LITERATURE

Anatomy:

Parts of male urethra;

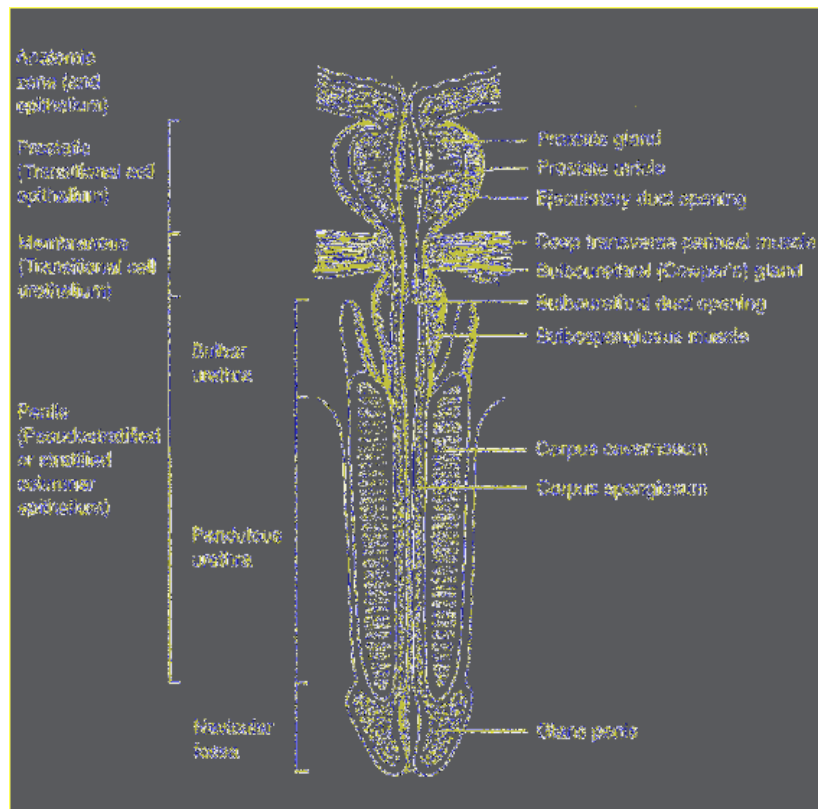
1. Anterior urethra
2. Posterior urethra

Parts of anterior urethra

- fossa navicularis
- penile urethra
- bulbar urethra

Parts of posterior urethra

- membranous urethra
- prostatic urethra



The corpus spongiosum, spongy tissue lies in ventral aspect of corpora cavernosa and it surrounds the urethra. Tunica albuginea of the corpus spongiosum has thinner tunica albuginea, decreased amount erectile tissue comparing to corpora cavernosa layer of tunica.

Tough Bucks' fascia immediately surrounds the tunica albuginea. On dorsal aspect of bucks fascia contains

1. Deep dorsal vein
2. Paired dorsal arteries
3. Br. dorsal nerves.

On ventral aspect, of corpora cavernosa buck's fascia divides and surrounds the corpus spongiosum. Fascia of buck joins glans penis distally. Proximally at pubis ischium and inferior fascia of the perineal membrane.

Anterior urethra extends from inferior fascia of urogenital diaphragm to external urethral meatus of penis.

Within the spongy erectile tissue of glans penis is the Fossa navicularis. distal to the attachment of ischiocavernosus musculature, there lies penile urethra but is surrounded by corpus spongiosum.

The bulbous urethra is covered by the ischiocavernosus musculature, surrounded by bulbospongiosus & corpus spongiosus.

Lining epithelium of male urethra:

- Prostatic urethra- transitional cell epithelium
- Membranous, bulbar, penile urethra- stratified or pseudo stratified columnar
- Fossa navicularis- stratified squamous epithelium.

Histology

Urethra formed by three layers

1. Mucosal layer.
2. Sub mucosal layer.
3. Muscular coat layer.

I. Mucosal layer:

As previously mentioned various parts of urethra lined by various type of mucosal lining.

II. Sub mucosal layer:

It extends throughout the length of the urethra. It has a rich vascular and erectile tissues

III. Muscular coat:

Muscular coat of prostatic and membranous urethra is a downward continuation of detrusor muscle layer of bladder. It is innervated by sympathetic nerve fibers. The sphincter urethra was formed by the striated muscle layer. It is surrounds the membranous urethra.

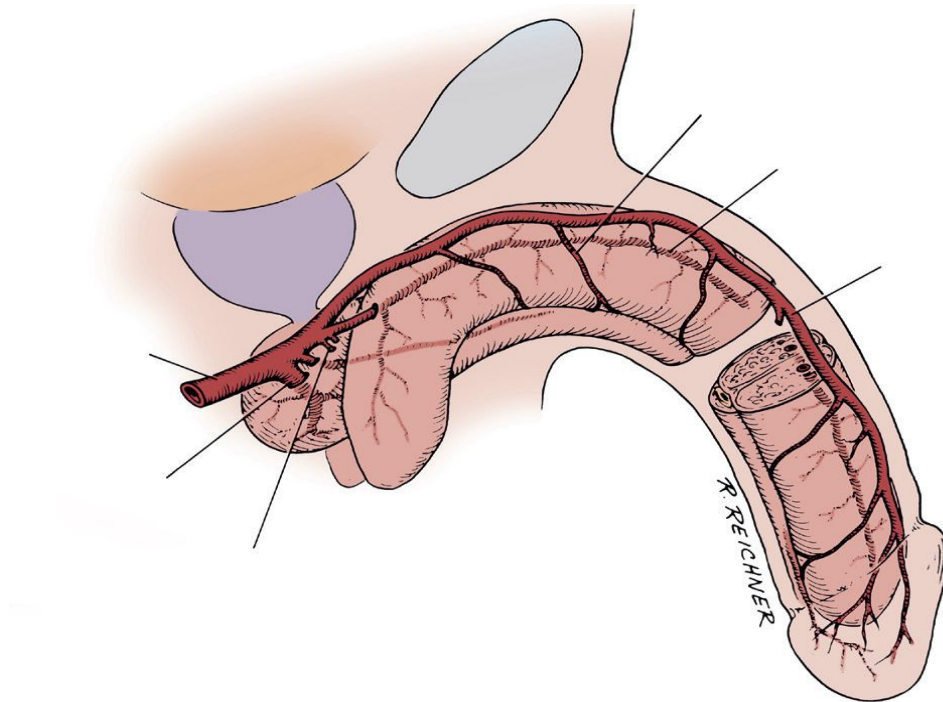
ARTERIAL SUPPLY:

Blood supply to deeper structures of anterior Urethra is from common penile artery. It is a continuation of internal pudendal artery. It gives two branches 1) perineal artery 2) posterior scrotal artery, after that named as common penile artery. Below the inferior pubic ramus, on its medial margin it continues.

At the bulb of urethra, it divides and gives off 3 branches

1. Bulbourethral artery
2. Dorsal artery
3. Cavernosal artery

ARTERIAL SUPPLY OF URETHRA



Bulbourethral artery, a short artery which pierce perineal membrane to enter bulbous spongiosus. It supplies urethra, glans and spongiosum.

On dorsal aspect of penis is dorsal artery, which related medially to deep dorsal vein and lies dorsal nerves laterally. It was uncoiled when the penis was erect. It gives off 3-10 circumflex branches. It accompanies the circumflex vein laterally. terminally on the glans is the branches arborize.

There is dual blood supply for corpus spongiosum. Proximally supplied by bulbar and circumcavernosal arteries ,distally by arborizations of dorsal penile artery.

Based on recent ultrasound studies , the urethral arteries are not typically located at 3 or 9 o clock positions(1). Urethral arteries have a variable position and location varies with equal distribution around the clock among patients. Thus urethrotomy location is not a matter, as it not too deep into the spongiosum.

Stricture disease

Etiology

Basically the involving the anterior urethra is caused by

1. Inflammatory disease of corpus spongiosum like Balanitis Xerotica obliterans (BXO), post gonococcal strictures.
2. Ischemia-common in patients after urological endoscopic procedures, patients with cardiovascular disease.
3. Traumatic scarring after blunt perineal trauma.
4. Hypospadias failure.

5. Congenital anomalies of the mucosal membrane, usually in the bulbar urethra with the corpus spongiosum not involved.

In industrialized countries stricture urethra occur due to blunt external perineal trauma(eg. Straddle injury) or instrumentation. In underdeveloped countries, majority are inflammatory and commonly seen in the bulbar and penile urethra.

analysis of the literature shows that more strictures are due to iatrogenic(33%),idiopathic(33%) and few are because of, trauma(19%) and inflammation(15%).⁽⁵⁾

strictures of the bulb are commonly seen(44% to 67%), followed by pendulous urethral strictures in 12% to 39%,combined in 6% to 28%, meatus or submeatal(0% to 23%),membranous (0 to 20%), and prostatic(0% to 4%).⁽⁶⁾

Pathogenesis

Usually stricture is a fibrotic reaction, with varying grades of fibrosis of spongiosum, that cause tissue of poorly compliance and caliber of urethra narrows . The normal urethra is covered of pseudostratified columnar epithelium. Below the basement membrane of corpus spongiosum is rich in vascular sinusoids

and smooth muscle. The connective tissue has fibroblast and an ECM that has collagen, , elastic fibers and glycoproteins. histologic changes mainly seen in the connective tissue. **Due to damage of epithelial and fibrosis of corpus spongiosum stricture results .**

Scott and Foote⁽²⁾ stated that after trauma the ulcerated epithelium covered by columnar epithelium which stratified . The myofibroblasts and giant cells infiltration produce collagen forming fibrosis.

Singh and Blandy⁽³⁾ in their study found increase in total amount of collagen leads to dense fibrotic stricture with decreased elasticity.

Baskin⁽⁴⁾ found that not the amount of collagen but change in subtype of collagen (increase in type III collagen) result in decreased elasticity and compliance of urethra.

In traumatic strictures ,dense scar with decreased elastic fibres seen.

When most stricture were gonococcal in origin it was nonetheless clear that a stricture did not necessarily follow an attack of gonorrhoea, and when it

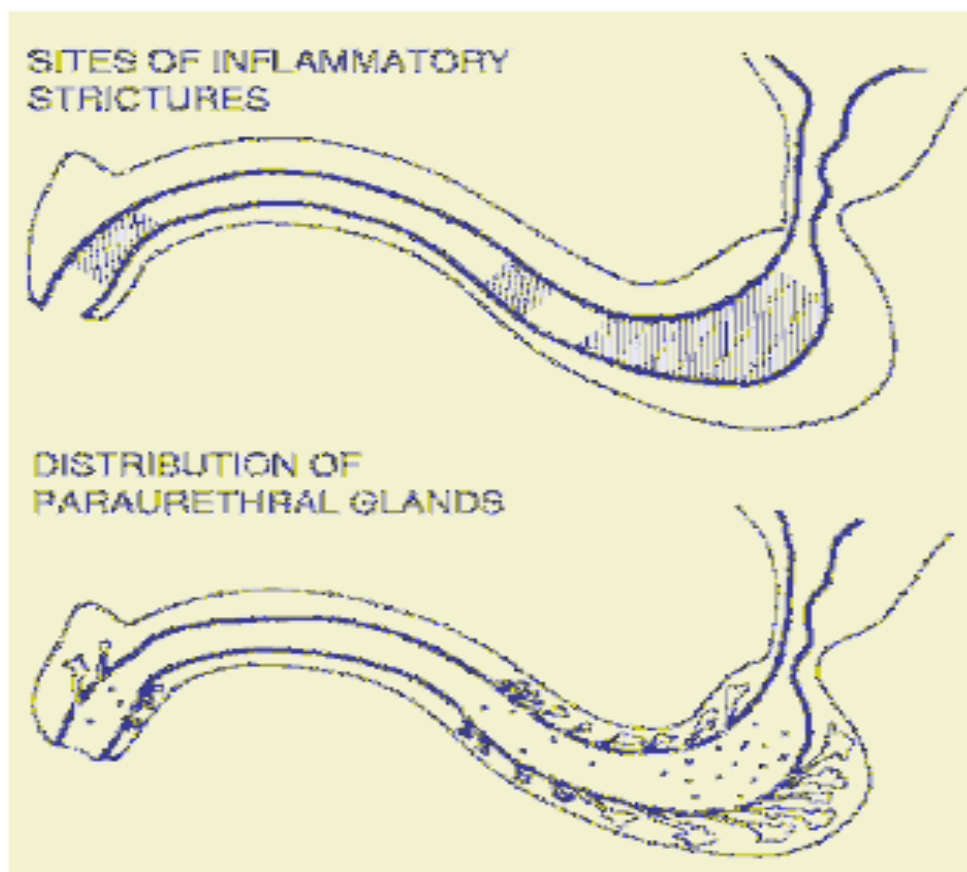
did the time lag could be considerable. Thus an episode of infection or trauma is not necessarily a direct cause of stricture.

Chambers et al. stated that first seen change in stricture of urethral disease due to **a change in feature of lining epithelium of urethra** from a pseudo-stratified type to a columnar epithelium. It has no waterproofing quality which seen in the pseudo-stratified type. So urine extravasation causing fibrosis.

Some loss of lining epithelium is an important cause leading to stricture development. Exposure of vascular spaces of corpus spongiosa to urine leads in superficial spongi thrombosis which develops to a spongiofibrosis. Few parts of a lining epithelium usually lead in narrowing of urethral lumen while healing. when margins of remaining epithelium are approximated during void pressure so that clefts of unepithelialized areas which heal by adhesion as well as bridging.

During urine voiding opens clefts, and this repeated process—combined with relatively slow proliferation—leads to gradual increase in underlying spongi thrombosis and later spongiofibrosis and formation Of stricture.

Singh and Blandy explained why inflammatory stricture is seen commonly in the middle-bulbar & distal part of penile segment urethra, because that most paraurethral glands are more in those areas. The corpus spongiosum fibrosis occurs first, caused directly by the extravasating urine into epithelium of urethra or by involving gland of urethra in some at specific sites, and extending further to into the spongiosum. Once started, fibrosis of corpus spongiosum develops to narrow the lumen and associated infection in to this, cause formation of small abscess within the glands, which lead to thick fibrosis and to peri-urethral extension.



Urethra lined by waterproof pseudo stratified columnar epithelium



Leaky columnar epithelium



Extravasation of urine and spongiofibrosis



Constriction of urethral lumen



Micro abscess in urethral glands



Periurethral extension of inflammation → More severe stricture

Spongiofibrosis

The surgical significance of established urethral spongiofibrosis is its high predisposition to progress to stricture formation when it is

inappropriately used in surgical repair. Thus it is the overall extent of the spongiofibrosis associated with a stricture and not simply the length of stricture itself-that should properly determine both the type and extent of an urethral repair required to achieve satisfactory long-term resolution. If the longitudinal extent of the urethral repair is limited only to the length that is actually strictured, as opposed to the length of the Spongiofibrotic abnormality, it commonly results in restenosis.

Severe Spongiofibrosis changes are often palpable and they are generally apparent urethrographically by a scarred reduction in the caliber of the urethral lumen and by the excavation of the ducts of the glands of the Littre and Cowper. Endoscopically spongiofibrotic urethra has a whitish colour-quite distinct from the normal urethra that is pink because underlying vascular Spongy tissue is seen through the translucent covering of the urothelium. However preoperative evaluation even by the Sonourethrogram offers only a guide line- the critical extend of the surgically significant Spongiofibrotic gray urethral abnormality may not be apparent until it can be accurately determine by the direct inspection at the time of operation when the urethra has been opened by the incision extending into truly pink urethra proximally and distally –when it is revealed by a well-defined thin layer of sub epithelial fibrosis that is clearly distinguishable.

With further narrowing of the lumen and if obstruction of outflow develops, secondary changes in the lower urinary tract seen, and also upper urinary tract. this obstruction a predispose to recurrent UTI and secondary infection of prostate and epididymis are common .if <50 yrs Upper tract complications are few .

Retrograde urethrography - used for evaluation of the urethra from the meatus to the proximal bulb portion. The VCUG assess posterior urethra.



Figure 1. RUG showing stricture bulbar urethra

Stricture characteristics

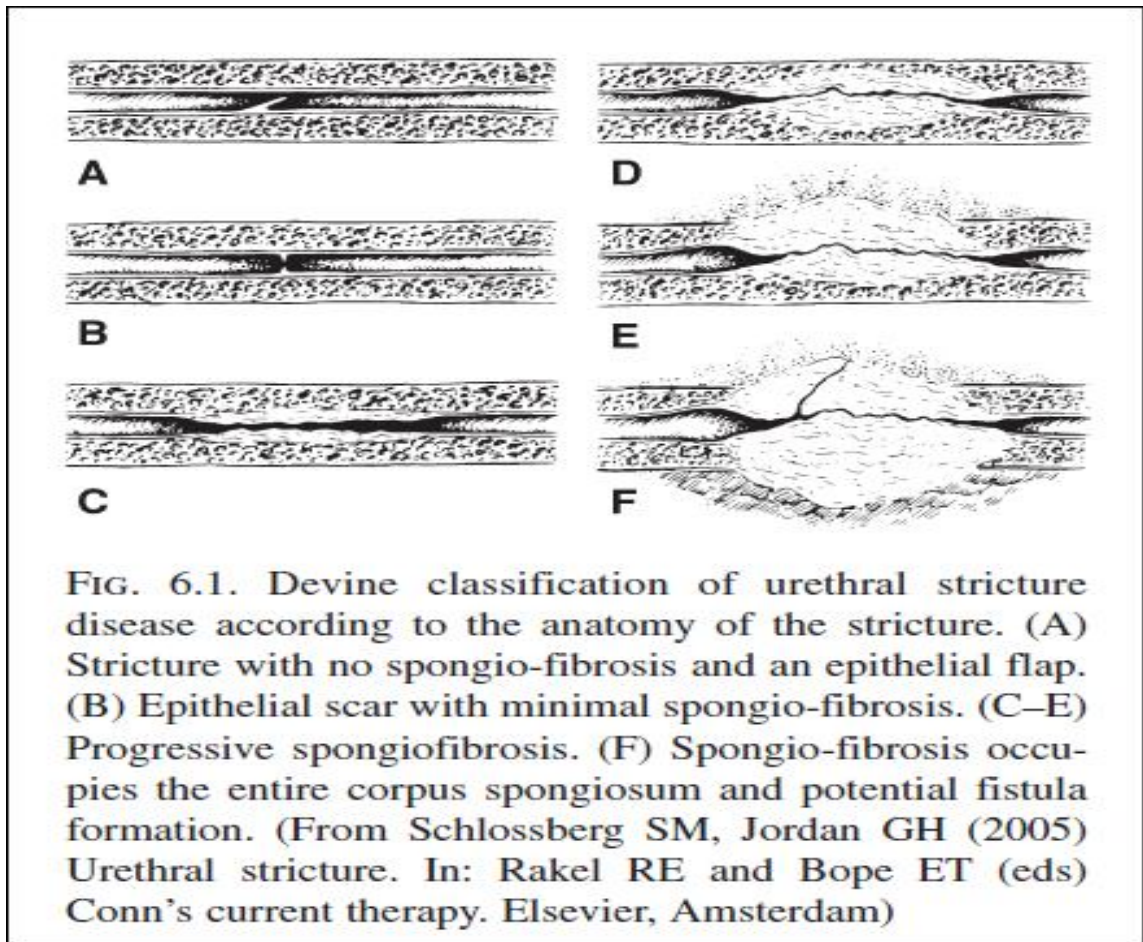
Strictures caused by instrumentation tend to occur at the membranous segment and penoscrotal junction. They are short and smooth type. Traumatic strictures are short, focal, and smooth seen in the bulbar urethra. Strictures of infectious cause which are irregular, longer, multiple and involve bulbar and penile urethra.

Sonourethrography is another modality used to image urethra. It has high accuracy in determining length of bulbar urethral stricture and degree of spongiofibrosis. Sites of fibrosis around urethra seen as hyperechoic.

MRI is useful in evaluation of posterior urethral trauma and periurethral soft tissue. Strictures become symptomatic at a lumen size below 16F.

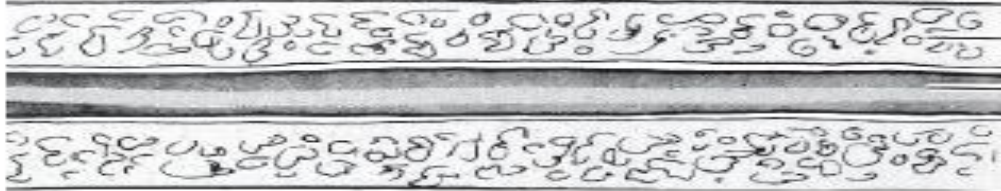
STRICTURE CLASSIFICATION

According to Devine⁽⁷⁾ 1983, who proposed a classification based on extent of fibrosis of corpus spongiosum. Jordan and Devine framed an algorithm for management with types of surgery or urethrotomy on basis of stage of stricture.

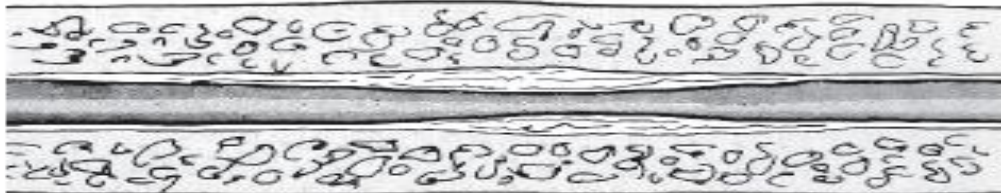


In 1988 ,McAninch proposed urethral stricture staging system based on sonographic appearance (fig.6.2)

Normal



Mild < 1/3 Lumen occluded



Moderate 1/3-1/2 Lumen occluded



Severe > 1/2 Lumen occluded

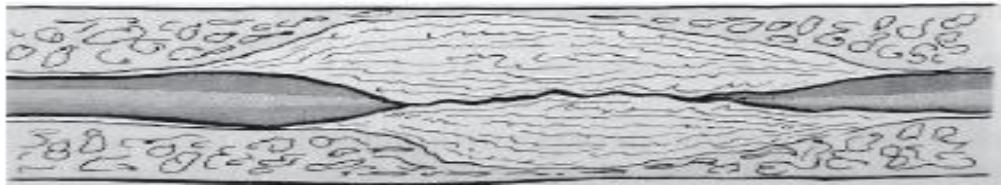
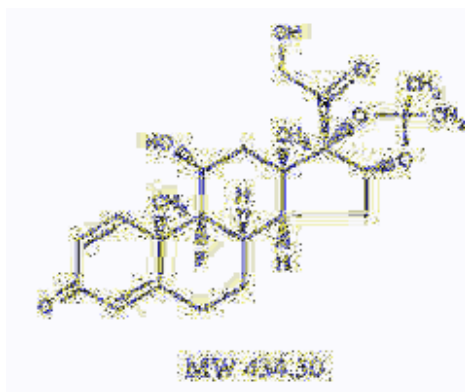


FIG. 6.2. Ultrasound classification of the degree of urethral occlusion, after McAninch and later modified by Chiou (From Ref. [10]).

PHARMACOLOGY OF TRIAMCINALONE

The chemical name for triamcinolone acetonide is 9-Fluoro-11 β ,16,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone. Its



structural formula is

It is available in white to cream-colored, powder having slight odor but it is insoluble on dissolving in water and but so nicely in alcohol.

Kenalog®-40 Injection (triamcinolone acetonide injectable suspension, USP)

is a synthetic glucocorticoid corticosteroid having anti-inflammatory

property. Every mL of the sterile aqueous suspension gave 40 mg

triamcinolone acetonide, along sodium chloride because of isotonicity,

0.99% (w/v) benzyl alcohol which act as preservative, 0.75%

carboxymethylcellulose sodium, and 0.04% polysorbate 80. to correct pH to

5.0-7.5 Sodium hydroxide or hydrochloric acid is present. During

production, nitrogen replaces air which inside the container

Kenalog-40 Injection (triamcinolone acetonide injectable suspension, USP) has an extended duration of effect which may be used for a long a period of several weeks. Giving the single intramuscular injection , 60 mg to 100 mg triamcinolone acetonide, within 24 to 48 hours suppression of adrenal gland forms.and but recovers usually in 30 to 40 days.



Hebert⁽⁸⁾ initially used the Local corticosteroid (triamcinalone) injection after internal urethrotomy¹. by reducing collagen levels and glycosaminoglycan formation and production of inflammatory mediators .steroids work.⁽⁹⁾

MANAGEMENT OF ANTERIOR URETHRAL STRICTURES

The minimally invasive treatment routinely used for managing strictures are dilation, direct vision internal urethrotomy(DVIU).

DIRECT VISION INTERNAL URETHROTOMY

The overall success rate of DVIU ranges from 66% to 90%⁽⁶⁾. it decreases drastically on follow up for long periods.

In already treated, more than(>2cm), multiple strictures, penile than bulbar strictures and patients with perioperative infections recurrence of stricture is high.

The main indications for dilation or DVIU are single site, <2cm strictures of bulbar site, without changes of inflammation and no previous treatment.

Specific contraindications to OIU are active infections, bleeding diathesis, suspicious of urethral malignancy.



Figure 2. Sachse urethrotome

TECHNIQUE:

DVIU can be done with cold knife or laser. Cold knife internal urethrotomy is done using sachse urethrotome with 0 or 12 degree telescope. Incision is done at 12 o' clock position and further incision until full thickness of stricture divided upto proximal normal urethra. Enter bladder and perform thorough cystoscopy. Bladder catheterised with 16fr foley.

Some do multiple incisions close together radially of full thickness of the stricture. However recurrence after multiple incisions don't vary significantly than single incision technique.

Different type of lasers are used for performing DVIU like Ho:YAG laser, Nd: YAG Laser, KTP laser.

Complications:

- Pyrexia(5%), septicemia 2%, extravasation 3%, bleeding 3%, retention 2%,
- Erectile dysfunction-2-11%⁽¹⁰⁾
- High flow priapism or a urethral internal pudendal artery fistula⁽¹¹⁻¹³⁾

DILATION

Dilatation of urethra by metal sounds or bougies, catheters of increasing size, filiform and followers, Amplatz dilators or an inflatable balloon. The aim of dilation is **to stretch the scar tissue** without producing more scarring. It is usually necessary to dilate to 20Fr / 24 Fr.

Stormont and associates reported a success rate at 3yr is 65% for the treatment by dilation and DVIU has 68% success rate, that both modes are equally effective for initial management of strictures of bulbar which are short.⁽¹⁴⁾

Most studies have reported that, recurrence after DVIU , it occurs early after the procedure, **in about 3 to 9 months**^(15,16,17,18). The most important parameter determines recurrence is duration of follow up.

Pansadoro and Emiliozzi ⁽¹⁹⁾ noted stricture recurrence within 12 mon. after DVIU in 56% recurses in <12 months, 26% at 12-24 months, at 24–36 months its 8%, during 36–60 months about 7%, and > 60months with 6% **rate**. **Steemkamp** and associates⁽²⁰⁾ found that after dilation or DVIU the risk of recurrence of strict. was high at 6 months and after 12 months it is less.

RISK FACTORS FOR RECURRENCE:

1. Etiology
2. Already treated stricture
3. Periurethral scarring
4. Length of the stricture
5. Caliber or diameter of the stricture
6. Number of strictures
7. Perioperative infections

PREVENTION OF RECURRENCE

1. Hydraulic self –dilation

Done by patient, who compress the urethra on& off during voiding which cause urethra dilatation.

2. Clean intermittent self catheterization

Twice a week for 1 month ,then once weekly, or once daily for 1 wk,then once weekly or once monthly^(21,22). Bodker and associates reported need for long term or life time CIC after DVIU .⁽²¹⁾

3. Clinic dilation

Start 10 days after urethrotomy, once aweek for 1 month, once at 3 months and 6 months, later once a year(Tunc and associates).

4. Steroids

Intralesional injection of steroid, weekly intra urethral instillation of steroid jelly.⁽²³⁾

5. Botulinum toxin

Injection of botulinum toxin type A following internal urethrotomy decreased scar formation (kehra et al)⁽²⁴⁾

6. Mitomycin C

Mitomycin C inhibits fibroblast proliferation and prevents scar formation.

7. Brachytherapy

Endourethral brachytherapy with 192 Iridium is a safe method to reduce restructure rate.⁽²⁵⁾

8. Injection of captopril

Holm- Nielson and colleagues reported recurrence rates from 50% to 75% during a 2 year follow up period after internal urethrotomy.⁽²⁶⁾

Hardec and coworkers reported that steroid injection decreased recurrence rate from 19.4% to 4.3%⁽²⁷⁾

In a recent randomized, placebo-controlled trial, Hosseini and colleagues injected triamcinolone for seventy patients who are doing CIC after internal urethrotomy. They started patients on a urethral catheterization program and used triamcinolone as lubrication. Thirty patients had inj. Of triamcinolone (experimental group) and 34 patients were using waterbased jelly injections (control group). Recurrence in both group were 30% (experiment) and 44%, respectively.⁽²⁸⁾

AIM OF THE STUDY

1. To study the effect of triamcinalone acetate injected intralesionally in patients undergoing internal urethrotomy (DVIU) for anterior urethral strictures
2. To collect short term data on the need for self calibration or dilatation and other adjuvant procedures in those patients in one year.

MATERIALS AND METHODS

It is a prospective study conducted in our institution from January 2013 to February 2014. After receiving ethical committee approval from our institution, around 50 patients with stricture of urethra who are symptomatic and presenting at our hospital were selected.

STUDY CENTRE

The study was conducted in Govt. Stanley medical college and hospital, Chennai -1.

STUDY DESIGN

This was a prospective experimental study. 50 patients of stricture urethra who are symptomatic, presenting at our hospital were segregated into two groups 25 in each containing group. The experimental

Group(D) were treated by cold knife internal urethrotomy with intralesional triamcinolone injection while the control group (C)

treated with urethrotomy alone. Postoperative results were compared between two groups.

INCLUSION CRITERIA

1. Anterior urethral stricture <2cm
2. Age 18-65 years

EXCLUSION CRITERIA

1. Completely obliterated strictures
2. Urethral strictures >2cm
3. Neurogenic bladder
4. History of systemic or immune disease
5. Patients already on steroids
6. Patient refusal

Preoperative work up

- Complete history
- Physical examination

- Examination of genitalia and perineum
- Urine culture and sensitivity
- USG KUB
- Uroflowmetry
- Retrograde urethrography

under general or spinal anesthesia procedure is done. Every patients received intravenous prophylactic antibiotics inj. Cefotaxim 1gm i.v preoperatively. Cystoscopy using 20 fr sheath and ureteric catheter of 5 fr passed through stricture portion into the bladder. Using sachse urethrotome and cold knife internal urethrotomy done at 12 o' clock position , bladder entered and thorough cystoscopy done. After cold knife urethrotomy ,80mg of injection triamcinalone (diluted with 6ml of distilled water to 8ml) was injected by cystoscopic injection needle (5 Fr size and 23 G needle size, cook medical Inc,) at 12, 3, 6, 9 o clock position 2ml at each site. After the procedure using Foleys catheter of 18 fr bladder catheterised for 5 days. Antibiotic was given till catheter was removed.

After the procedure patients were evaluated based on history as well as uroflowmetry. The urine cultures were done after surgery on the second POD. The patients Who are positive for culture received appropriate antibiotics. AUG was done in follow up period if the patient suffer by difficulty in voiding symptoms or the PFR was below 15ml/sec.

Followed up regularly 1 at 3, 6, 12 months and when present with symptoms.if Any symptoms suspicious for recurrence were found, such as thin stream of urine, AUR, and burning micturition. The treatment was reported successful if they don't complain any voiding symptoms and had a PFR >15ml/sec for a volume of urine of atleast 150ml. calibration of urethra , urethroscopy or retrograde urethrogram was done in case of difficulty to pass urine or reduction in Qmax flow.

STATISTICAL ANALYSIS

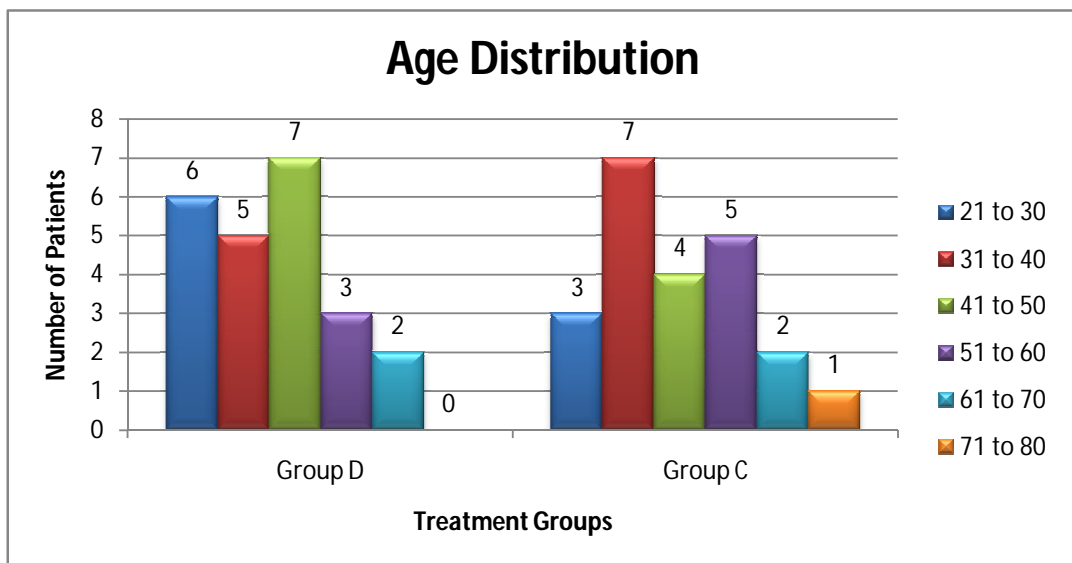
Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t-test and categorical variables were analysed with the Chi-Square Test with Yates correction. Statistical significance was taken as $P < 0.05$. The data was analysed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

OBSERVATION AND RESULTS

Two patients in group D(Triamcinalone group) and 3 patients in Group C (Control) were lost to follow up and therefore they were , excluded from our study. Data analysis were done from reports collected of 23 patients and 22 patients in triamcinalone (D)and control group(C) who fulfilled the follow up period of 12 months after internal internal urethrotomy.

There was no complication that could be attributed to triamcinalone injection. There were no significant perioperative complications related to the procedure. We noted that frequency , thin stream of urine and burning micturition were the most common presentation.

Age

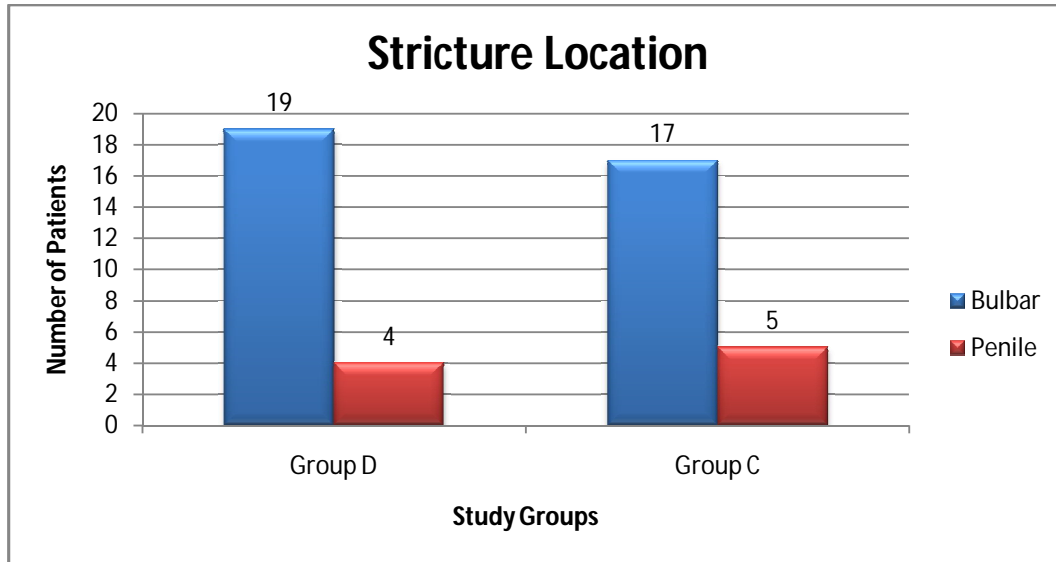


Age	Group D	%	Group C	%
21 to 30	6	26.09	3	13.64
31 to 40	5	21.74	7	31.82
41 to 50	7	30.43	4	18.18
51 to 60	3	13.04	5	22.73
61 to 70	2	8.70	2	9.09
71 to 80	0	0.00	1	4.55
Total	23	100	22	100

Age	Group D	Group C
Mean	40.84	46.96
SD	12.63	12.65
N	23	22
P value	0.1118	

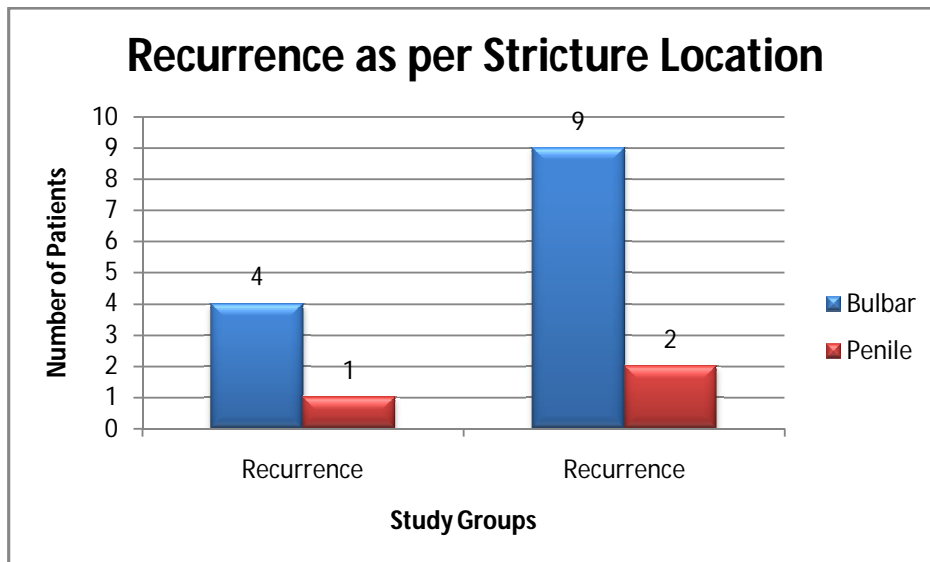
- In our study majority of the patients are in the age groups 31 to 40 and 41-50 years
- The mean age in Group D is 40.84 years compared to 46.96 years in Group C.
- Since the p-value is 0.1118, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no difference between the means.
- This establishes the fact that in spite of difference in age in each studygroup, we are dealing with statistically similar groups in relation to age

Stricture Location



Stricture Location	Group D	%	Group C	%
Bulbar	19	82.61	17	77.27
Penile	4	17.39	5	22.73
Total	23	100	22	100
P value	0.2001			

- 19(82.61%) of the Group D patients had stricture in bulbar urethra
- 17(77.27%) of the Group C patients had stricture in bulbar urethra
- Since the p-value is 0.2001, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the proportions of study groups in relation to stricture location

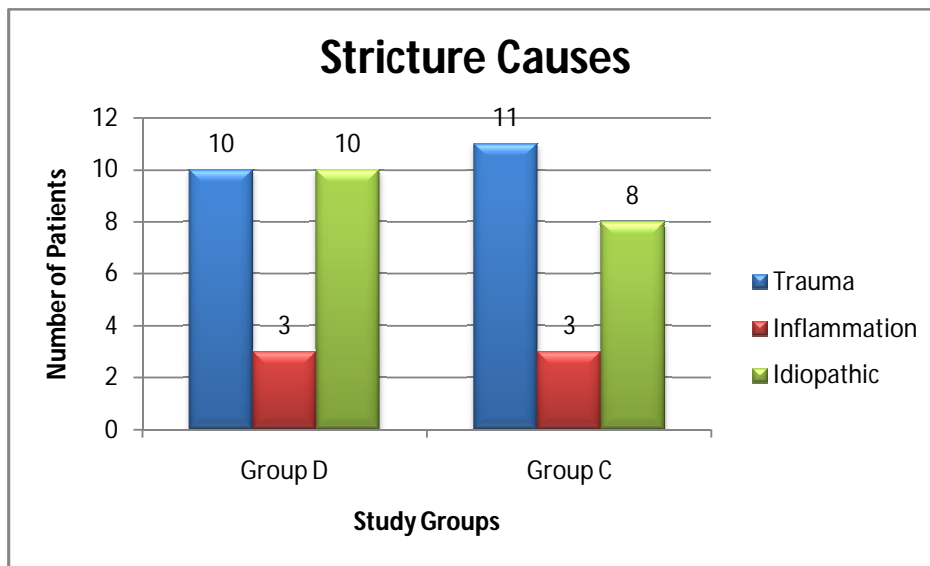


Recurrence as per Stricture Location	Group D	%	Group C	%
Bulbar	4	80.00	9	81.82
Penile	1	20.00	2	18.18
Total	5	100	11	100
P value	0.931			

- .4(80%) of the Group D patients with stricture in bulbar urethra had recurrence of stricture
- 9(81.82%) of the Group C patients with stricture in bulbar urethra had recurrence of stricture after intervention
- Since the p-value is 0.931, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is nostatistical difference between the

proportions of study groups in relation to recurrence as per stricture location

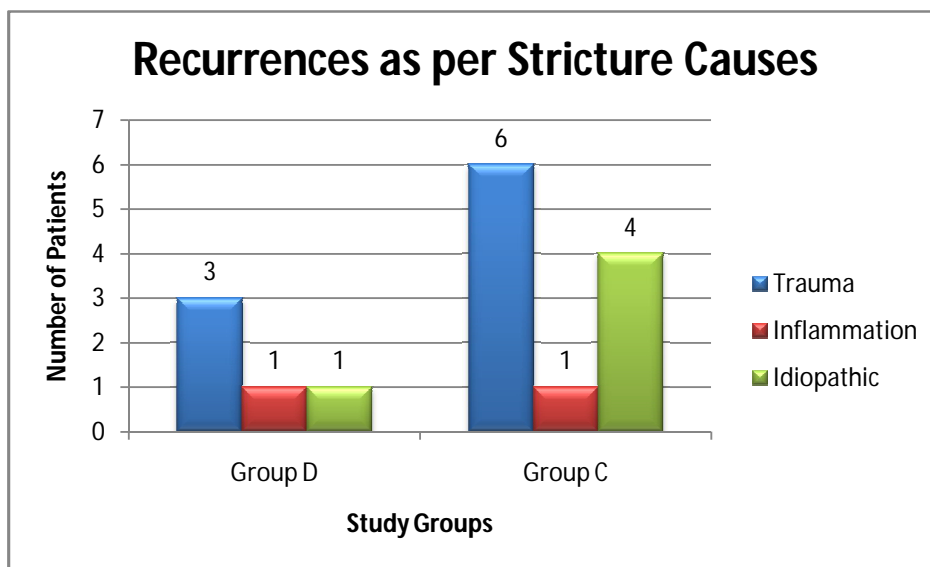
Stricture Causes



Stricture Causes	Group D	%	Group C	%
Trauma	10	43.48	11	50.00
Inflammation	3	13.04	3	13.64
Idiopathic	10	43.48	8	36.36
Total	23	100	22	100
P value	0.248			

- 10(43.48%) of the Group D patients had stricture due to traumatic aetiology
- 11(50%) of the Group C patients had stricture due to traumatic aetiology

- Since the p-value is 0.248, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the proportions of study groups in relation to stricture causes

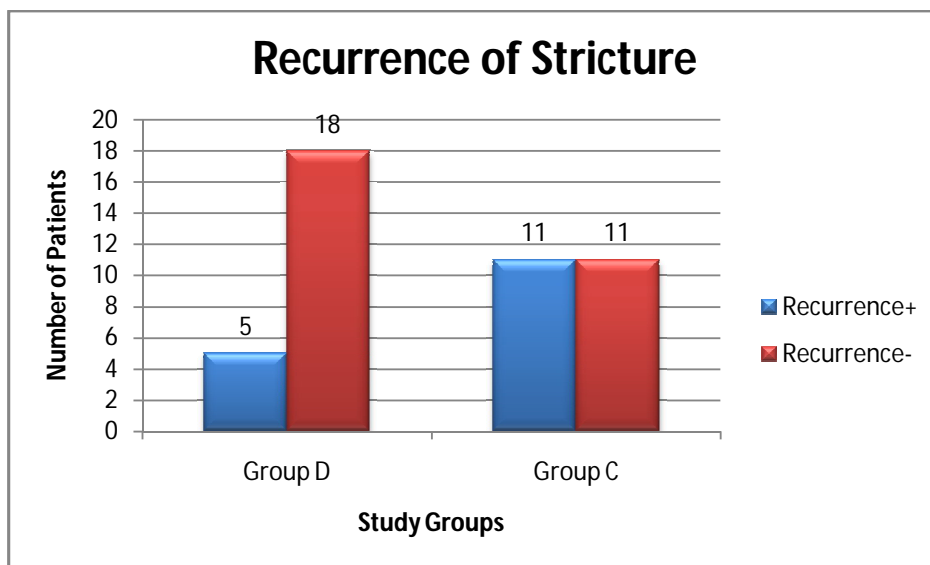


Recurrences as per Stricture Causes	Group D	%	Group C	%
Trauma	3	60.00	6	54.55
Inflammation	1	20.00	1	9.09
Idiopathic	1	20.00	4	36.36
Total	5	100	11	100
P value	0.726			

- 3(60%) of the Group D patients with stricture due to trauma had recurrence of stricture after intervention

- 6(54.55%) of the Group C patients with stricture due to trauma had recurrence of stricture after intervention
- Since the p-value is 0.726, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the proportions of study groups in relation to recurrence as per stricture causes

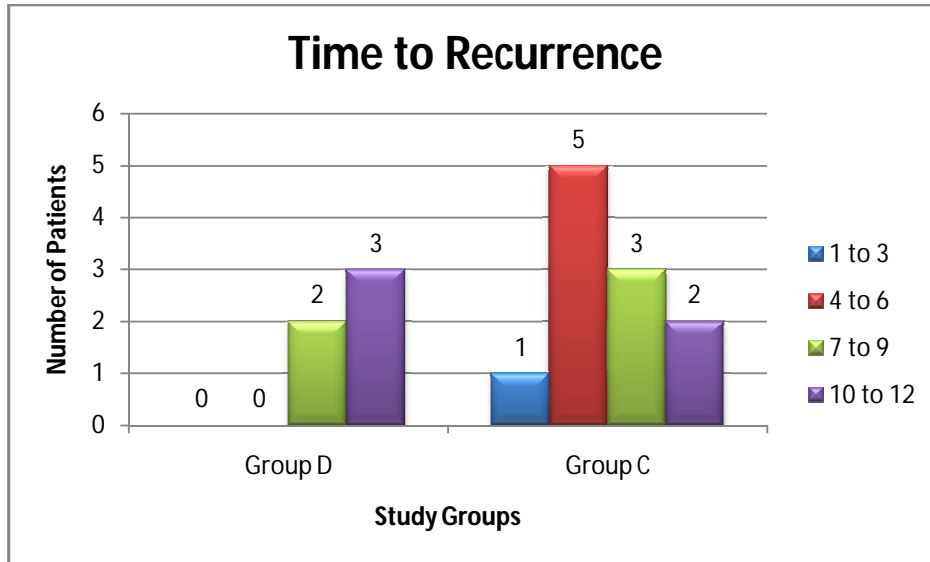
Recurrence of Stricture



Recurrence of Stricture	Group D	%	Group C	%
Recurrence+	5	21.74	11	50.00
Recurrence-	18	78.26	11	50.00
Total	23	100	22	100
P value	0.048*			

- 5(21.74%) of the Group D patients had recurrence of stricture after intervention
- 11(50%) of the Group C patients had recurrence of stricture after intervention
- Since the p-value is **0.048**, i.e. lesser than 0.05 (or 5 percent), it can be concluded that there is difference between the proportions of study groups in relation to recurrence as per stricture causes
- By conventional criteria the association between the study groups and recurrence of stricture is considered to be statistically significant .
- In contrast, we can conclude that the cold knife internal urethrotomy with intralesional triamcinolone injection Technique is superior to the internal urethrotomy Technique in terms of preventing recurrence of stricture with **an Overall success rate of 78.26 % in Group D and 11% in Group C**

Time to Recurrence



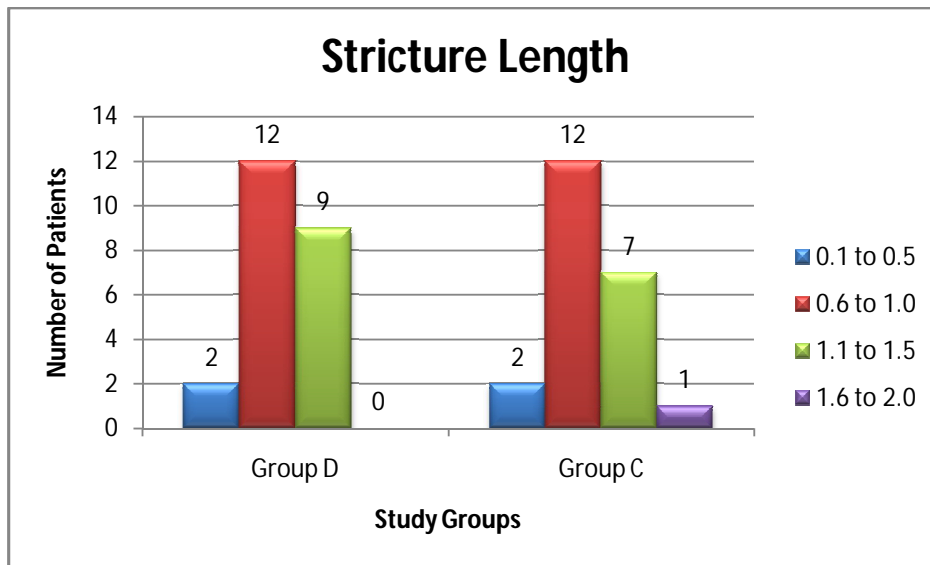
Stricture Causes	Group D	%	Group C	%
1 to 3	0	0	1	9.09
4 to 6	0	0	5	45.45
7 to 9	2	40	3	27.27
10 to 12	3	60	2	18.18
Total	23	100	22	100

Time to Recurrence (in months)	Group D	Group C
Mean	9.6	7.09
SD	1.14	2.06
N	23	22
P value	0.0.017*	

- 3(60%) of the Group D patients had recurrence of stricture after intervention between 10 to 12 months
- 5(45.45%) of the Group C patients had recurrence of stricture after intervention between 4 to 6 months
- The mean Time to Recurrence in Group D is 9.6 months compared to 7.09 months in Group C.
- Since the p-value is 0.017, i.e. lesser than 0.05 (or 5 percent), it can be concluded that there is difference between the means and proportions of study groups in relation to time taken for recurrence of stricture after intervention
- By conventional criteria the association between the study groups and time taken for recurrence of stricture after intervention is considered to be statistically significant
- In contrast, we can conclude that the cold knife internal urethrotomy with intralesional triamcinolone injection Technique is superior to the plain urethrotomy Technique in terms of Time taken for delay in recurrence of stricture after intervention

The time taken for developing recurrence of stricture after intervention is 2.51 months delayed in Group D compared to Group C.

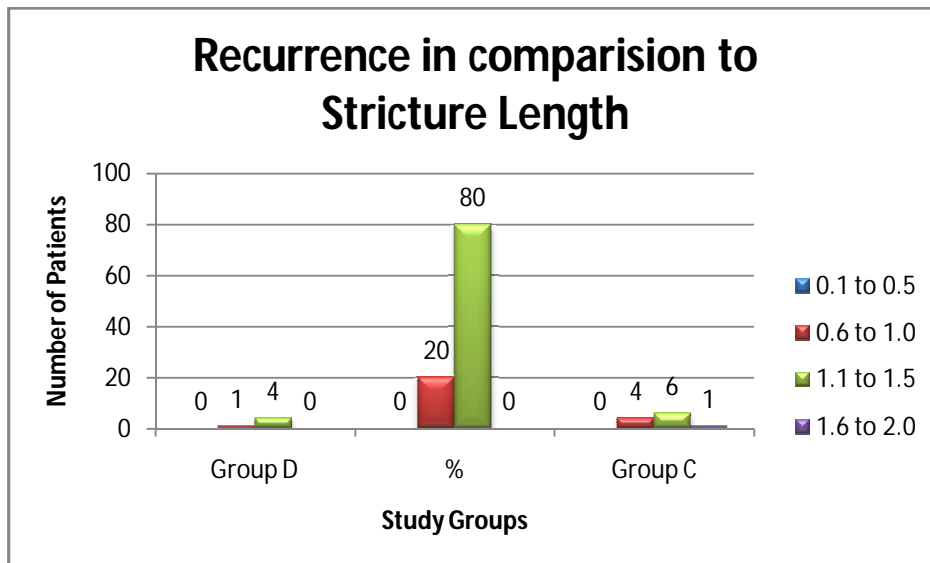
Stricture Length



Stricture Length (in cms)	Group D	%	Group C	%
0.1 to 0.5	2	8.70	2	9.09
0.6 to 1.0	12	52.17	12	54.55
1.1 to 1.5	9	39.13	7	31.82
1.6 to 2.0	0	0.00	1	4.55
Total	23	100	22	100

Stricture Length (in cms)	Group D	Group C
Mean	1.04	1.12
SD	0.25	0.31
N	23	22
P value	0.0.3597	

- 12(52.17%) of the Group D patients had stricture length between 0.6 to 1 cm
- 12(54.55%) of the Group C patients had had stricture length between 0.6 to 1 cm
- The mean stricture length in Group D is 1.04cm compared to 1.12cm in Group C.
- Since the p-value is 0.3597, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no difference between the means and proportions of study groups in relation to the stricture length



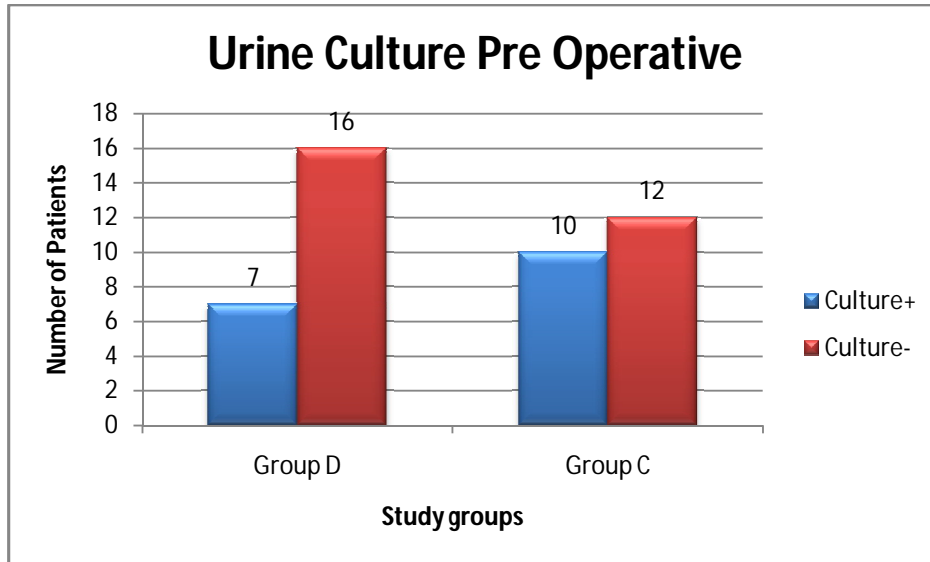
Recurrence in Comparison to Stricture Length	Group D	%	Group C	%
0.1 to 0.5	0	0	0	0
0.6 to 1.0	1	20	4	36.36
1.1 to 1.5	4	80	6	54.55
1.6 to 2.0	0	0	1	9.09
Total	5	100	11	100
P value	0.575			

In group D patients with stricture <1cm had recurrence of 20% and patients with 1-2cm stricture had a recurrence of 80%

In group C patients with recurrence with <1cm length of stricture was 36.36% and in stricture 1-2cm recurrence is about 54.55%

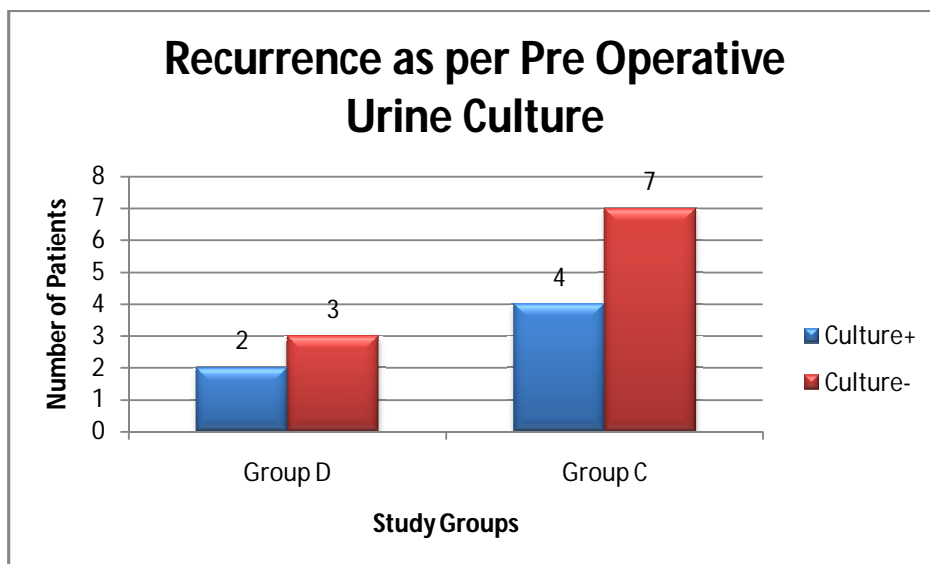
- 4(80%) of the Group D patients with stricture length 1.1 to 1.5cm had recurrence of stricture
- 6(54.55%) of the Group C patients with stricture length 1.1 to 1.5cm had recurrence of stricture
- Since the p-value is 0.575, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the proportions of study groups in relation to recurrence as per stricture length

Urine Culture



Urine Culture Pre Operative	Group D	%	Group C	%
Culture+	7	30.43	10	45.45
Culture-	16	69.57	12	54.55
Total	23	100	22	100
P value	0.299			

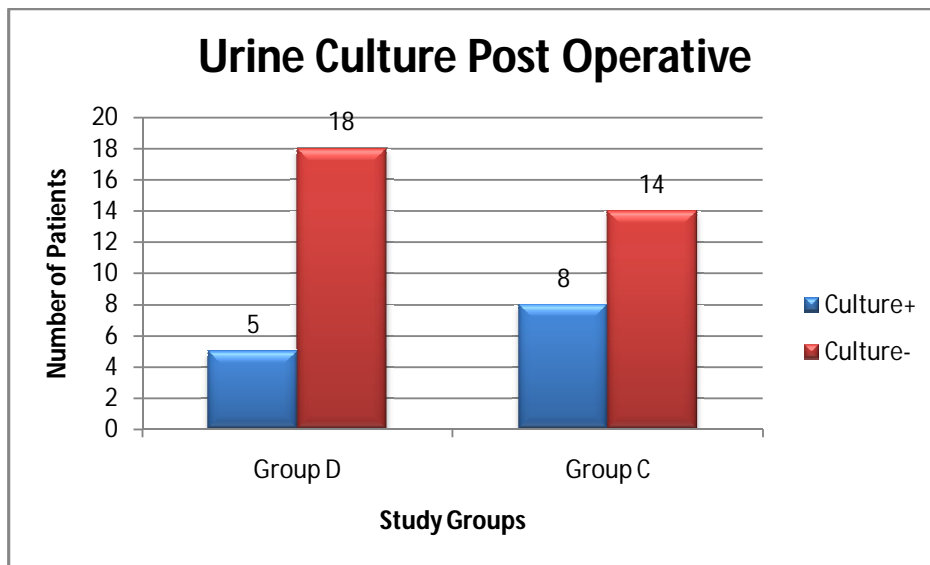
- 7(30.43%) of the Group D patients had Urine culture positive pre operatively
- 10(45.45%) of the Group C patients had Urine culture positive pre operatively
- Since the p-value is 0.299, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the proportions of study groups in relation to positive urine culture pre operatively



Recurrence as per Pre Operative Urine Culture	Group D	%	Group C	%
Culture+	2	40	4	36.36
Culture-	3	60	7	63.64
Total	5	100	11	100
P value	0.889			

- 2(40%) of the Group D patients with Urine culture positive pre operatively had recurrence of stricture after intervention
- 4(36.36%) of the Group C patients with Urine culture positive pre operatively had recurrence of stricture after intervention
- Since the p-value is 0.889, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the

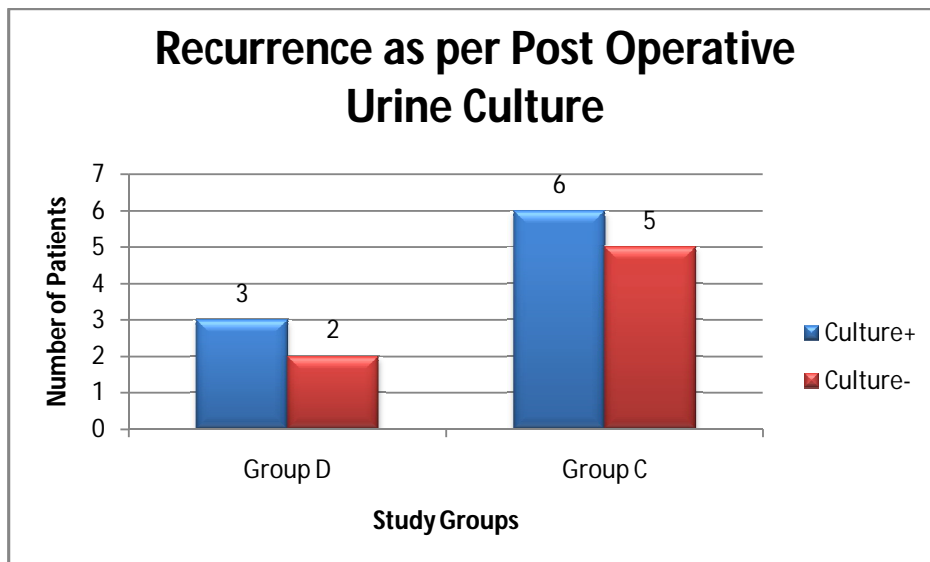
proportions of study groups in relation to positive urine culture pre operatively and recurrence of stricture after intervention



Urine Culture Post Operative	Group D	%	Group C	%
Culture+	5	21.74	8	36.36
Culture-	18	78.26	14	63.64
Total	23	100	22	100
P value	0.279			

- 5(21.74%) of the Group D patients had Urine culture positive post operatively

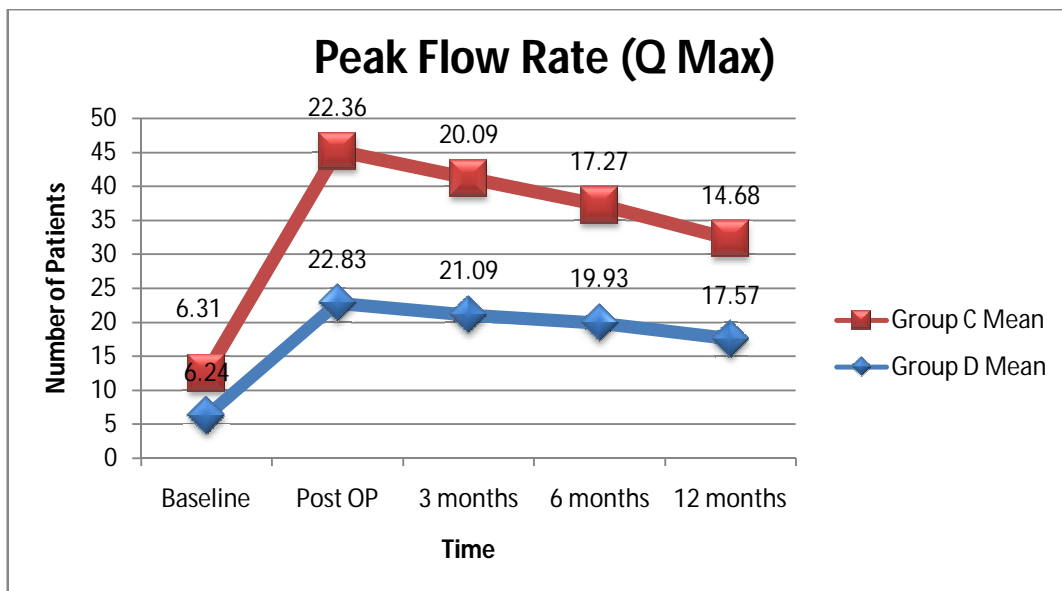
- 8(36.36%) of the Group C patients had Urine culture positive post operatively
- Since the p-value is 0.279, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the proportions of study groups in relation to positive urine culture post operatively



Recurrence as per Post Operative Urine Culture	Group D	%	Group C	%
Culture+	3	60	6	54.55
Culture-	2	40	5	45.45
Total	5	100	11	100
P value	0.838			

- 3(60%) of the Group D patients with Urine culture positive post operatively had recurrence of stricture after intervention
- 6(54.55%) of the Group C patients with Urine culture positive post operatively had recurrence of stricture after intervention
- Since the p-value is 0.839, i.e. greater than 0.05 (or 5 percent), it can be concluded that there is no statistical difference between the proportion of study groups in relation to positive urine culture post operatively and recurrence of stricture after intervention

Peak Flow Rate (Q Max)



Peak Flow	Group D			Group C			P value
	Mean	SD	N	Mean	SD	N	
Baseline	6.24	2.20	23	6.31	1.62	22	0.9037
Post OP	22.83	2.17	23	22.36	2.59	22	0.5167
3 months	21.09	2.09	23	20.09	3.46	22	0.2531
6 months	19.93	2.17	23	17.27	5.20	22	0.0345*
12 months	17.57	3.95	23	14.68	5.27	22	0.0451*

- The mean peak flow rate at the end of 9 months after intervention in Group D is 19.93ml compared to 17.27ml in Group C.
- Since the p-value is 0.0345, i.e. lesser than 0.05 (or 5 percent), it can be concluded that there is difference between the means and proportions of study groups in relation to peak flow rate 9 months after intervention

- The mean peak flow rate at the end of 12 months after intervention in Group D is 17.57ml compared to 14.68ml in Group C.
- Since the p-value is 0.0451, i.e. lesser than 0.05 (or 5 percent), it can be concluded that there is difference between the means and proportions of study groups in relation to peak flow rate 12 months after intervention
- By conventional criteria the association between the study groups and peak flow rate 9 and 12 months after intervention is considered to be statistically significant
- In contrast, we can conclude that the cold knife internal urethrotomy with intralesional triamcinolone injection Technique is superior to the plain urethrotomy Technique in terms of better peak flow rate.
- The peak flow rate stricture after 9 months after intervention is 2.66 ml more in Group D compared to Group C
- The peak flow rate stricture after 12 months after intervention is 2.89 ml more in Group D compared to Group C

DISCUSSION

The incidence of stricture urethra in male is about 0.6%(29). The most important complication of treatment of strictures is recurrence.(30).the causes for stricture being trauma, catheterization,instrumentation,chronic inflammatory disease like BXO,and sexually transmitted diseases. Most sytricture urethra are caused by idiopathic etiology and mostly due to unnoticed childhood trauma(31).

Cut the stricture and anastamosis end to end of has cure rate of 90-95%. But internal urethrotomy is a simple procedure in treatment of stricture disease and is followed as first treatment modality,though the success rate is 33% by 10 years which was lower to urethroplasty on long follow up.(32)

Internal urethrotomy act by setting apart fibrosed epithelium so that while healing starts and finished by secondary intention occurs.if epithelialization occurs completely before contraction of wound,urethrotomy will be successful but when will stricture recures is if contraction of wound occurs before completion of epithelialisation

If any drug or procedure which delays wound contracture would result in delay appearance of stricture .Triamcinalone acetonide , which has strong anti-inflammatory action reduce collagen pdt. and stops fibroblast

proliferation at level of wound tissue.this was the reason why for giving intralesional steroid after internal urethrotomy of my work

The follow up period in our study was 12 months from last internal urethrotomy. to assessing the success of internal urethrotomy vs recurrence we have to follow up for long term. Every year success rate decreases by of 10 to 20 % per year is noted after DVIU ,which may continue till upto five year. Following DVIU recurrence rate of 35% to 60% have been reported

Holm -Nielsen and colleagues(36) reported 50% to 75% recurrence during a two year follow up. The overall recurrence rate in our study was for (1 year)35.5% , recurrence in control group was 50% which is consistent with Holm-Nielsen and colleagues. The lower recurrence reason may be due to short follow up period in our study.

According to **Naude et al, (33).** most of the recurrence occurs during 3 to 12 months after internal urethrotomy. In our study recurrence in the control group(C) was 50% compared to 21.7% in triamcinalone group(D). There was significantly decrease in recurrence rate in group D(Triamcinalone group) compared to group C **Recurrence rate between the groups in our study reached statistically significant value (p=0.048).**

The mean time to recurrence in group D is 9.6 months compared to 7.09 months in group C which reached a statistically significant value (p=0.017).

Rapp et al ⁽³⁵⁾ in their survey found that for strictures <1cm ,most prefer internal urethrotomy and for stricture > 2cm , primary excision and anastomosis is preferred (success rate >95%). In our study ,the mean stricture length in group D was 1.04cm, in group C was 1.12 cm , which did not show any statistically significant value (p=0.359). In our study stricture < 1cm showed a recurrence rate of 20% in group D and 36.36% in group C. For stricture >1cm recurrence in group D 80% and in group C was 63%. Strictures less than 1 cm showed less recurrence rate than strictures between 1-2cm between the groups.this was in according to Rapp et al study.

Shirazi et al ⁽³⁷⁾ used captopril gel after DVIU with good results,but heterogeneity of patients makes interpretation of their results difficult.

Santosh kumar et al ⁽³⁸⁾ reported a success rate of 76% with triamcinalone injection following Ho: YAG laser internal urethrotomy.

Based **on etiology** , success rates with iatrogenic cause for stricture has higher success rate than with post-traumatic or post inflammatory cause.⁽³⁸⁾ In our study, the etiology of stricture was not significantly associated with outcome of cold knife internal urethrotomy (p=0.726). **The recurrence rate was found to be independent of the age of the patient , duration of symptoms, etiology of stricture, location of stricture(penile or bulbar).**

Kamp et al,⁽³⁴⁾ in their study found most of the recurrences were seen in strictures >1.5cm. In our study better outcome in strictures less than <1cm (recurrence -20%) is in accordance with study of **Rourke and Jordan**⁽³⁹⁾ ,found for strictures <1cm with minimal spongiofibrosis, have better results.

Hosseini et al,⁽⁴⁰⁾ reported good results in short strictures<1cm(recurrence 4.2%), compared to longer ones (recurrence 42.9%). Many studies have shown that endoscopic procedures for short strictures have better outcome than for longer stricture,with success rate of 85 to 87% for <1 cm strictures⁽³⁸⁾.Our study has a success rate of 80% for stricture <1cm.

Stricture recurrence found to be directly proportional to length of stricture. **Pansadoro and Emiliozzi**⁽⁴¹⁾ showed recurrence rate higher for > 1cm stricture.rate of recurrence is about 51 to 72% in many studies.⁽⁴²⁻⁴⁴⁾

In our study the recurrence rate for stricture < 1cm was 20% and for strictures 1-2cm the recurrence rate was 80%. This was in accordance to Pansadaro et al study.

Urinary tract infection in post op period found to affect the results in our study. Out of 12 patients who had urine culture positivity, 7 had recurrence (58.3%). Of 33 patients with sterile urine, 9 had recurrence (27.2%), but did not show statistically significance between the groups (p=0.08)

Boccon Gibod and Le Portz ⁽⁴²⁾ revealed length, location, cause of stricture and UTI were factors affecting outcome.

The recurrence rate after DVIU ranges from 30 to 58%. To reduce the recurrence rate with DVIU, various procedures like urethrotomy combined with hydraulic self dilatation, intra urethral mitomycin C, intraurethral captopril gel etc are followed. One such technique is injection of steroids with internal urethrotomy.

Nabi and Dogra ⁽⁴⁵⁾ study revealed, use of intralesional steroid and Nd:YAG laser in the treatment of traumatic prostatic and supraprostatic

strictures. During mean follow-up of 23 months, all 3 patients were asymptomatic and voiding well and were found to have normal results on cystoscopy, urethroscopy, and uroflowmetry done at 3 months.

Hosseini et al. ⁽⁴⁶⁾ compared patients undergoing clean intermittent catheterization with or without triamcinolone ointment following internal urethrotomy. At a follow-up of 12 months, recurrence was noted in 30% in the triamcinolone group compared with 44% in the other.

LIMITATIONS OF OUR STUDY

The limitations of our study is small number of patients and short follow up period (12 months). Follow up in our study covered the critical period of recurrence usually 18 months as stated by **Gucuk et al.** ⁽⁴⁷⁾.

A larger , randomized controlled study with longer follow up is required to confirm these findings and to establish the efficacy of triamcinalone and cold knife internal urethrotomy.

CONCLUSION

- From our study we conclude that injection of steroid triamcinalone following internal urethrotomy **decrease the recurrence rate of stricture as well as delays the time to recurrence** when compared to internal urethrotomy alone for the treatment of short segment urethral strictures(<2cm).
- To achieve curative and long-term effects, this technique of injection of steroid following internal urethrotomy has to be conducted on a large group of patients with long duration of follow up and special emphasis on objective verification of the safety and efficacy profile.
- Injection of steroid at stricture site can be considered as safe and effective adjuvant modality after internal urethrotomy.

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EFFECTS OF INTRALESIONAL TRIAMCINALONE INJECTION

BY 18112551 M.CH. UROLOGY RAJA RAJAN E.P. PICHANDI

19%
SIMILAR--
OUT OF 0

Match Overview



INTRODUCTION

stricture disease of urethra is always a challenge for almost all practicing urologists. Treatment options available such as dilatation,

DVIU, placement of stent, single or various stages of urethroplasty.

Management by endoscopy is routinely done first for short bulbar

urethral strictures before other modality of treatment. The reported success

rate of single DVIU is **20 to 60 %**. DVIU don't produce epithelial

approximation but it separates scarred epithelium so, wound heals by

secondary intention. If wound contraction takes place before full

epithelialisation, it significantly narrows lumen and result in recurrence.

Injection of steroid triamcinolone intralesionally following internal

urethrotomy, decrease formation of scar by enhancing endogenous

production of collagenase and obviates scar formation. In our study we

analysed the outcome of injection of steroid (triamcinolone)& urethral

stricture recurrence after DVIU. We analysed time duration between VIU

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INSTITUTIONAL ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Effects of intralesional triamcinalone injection following Internal^Urethrotomy in treatment of stricture urethra : A Prospective Clinical Study

Principal Investigator : Dr.E.P. Rajarajan

Designation : PG in MCh (Urology)

Department : Department of Urology
Government Stanley Medical College,
Chennai-1

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 07.02.2013 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.


MEMBER SECRETARY,
IEC, SMC, CHENNAI

APPENDIX

PROFORMA

DOA: DOS: UNIT :
Name of Patient:
Age: **Sex: M/F** **IP No.**

Address & Phone No:

History:

- Straining to void/LUTS symptoms
- Fever
- Dysuria
- H/o Pyuria/Hematuria/Calculuria
- H/o trauma/Acute Urinary retention/Indwelling catheter /instrumentation
- Diabetes mellitus/Hypertension/Tuberculosis
- Previous manipulation/Procedure
- Use of steroids
- H/o systemic or immune disease
- DM/HT/TB/BA/IHD

Clinical Examination:

Pallor/Pedal edema/Fever/Lymphadenopathy

Pulse: BP:

CVS: RS:

P/A

Genitals:

DRE:

Pre OP Investigation:

CBC	URINE R/E
RFT	URINE C/S
Uroflowmetry Peakflow- Mean flow- Voided volume /PVR	USG KUB
Ascending urethrogram	
MCU	
Cystoscopy	
HIV/VDRL/HBsAg	

Diagnosis :**Procedure:****Post Op:**

General Condition PR: BP: Temperature:

Investigation:

Catheter removal after 5 – 7 Days

Follow up:

Uroflow	After catheter removal	3 Month	6 Month	1 Year
PF MF Volume /PVR				
AUG				

நோயாளிகளுக்கான ஆலோசனை

சிறு நீர் நோயாளி சிறுநீர் கழிக்கும் பாதையில் சுருக்கம் மற்றும் அடைப்பு ,
தொற்று நோய் கிருமிகள் , விபத்துக்கள் மற்றும்
பலவகையான காரணங்களால் ஏற்படுகிறது. அந்த அடைப்பிற்கு ஏற்றவாறு
சிறு நீர் வரும் பாதை வழியாகவே அதை கிழித்து அறுவை சிகிச்சை
செய்யப்படுகிறது . இருப்பினும் அந்த அடைப்பு மீண்டும் வர வாய்ப்பு உள்ளது.
அதை தடுப்பதற்கு அறுவை சிகிச்சையின் போது அந்த இடத்தில்
த்ரியாம்சினலோன் என்னும் மருந்து செலுத்தினால் அந்த அடைப்பு மீண்டும்
வரும் வாய்ப்பு குறைகிறது மற்றும் அதனால் ஏற்படும் நன்மைகள் பற்றிய
ஒரு
ஆய்வினை மேற்கொண்டு உள்ளேன். இந்த கண்காணிக்கப்பட்ட மருத்துவ
ஆய்விற்கு தாங்களும் பதிவு செய்து தங்களது முழு ஒத்துழைப்பை நல்குமாறு
தங்களை அன்புடன் கேட்டுக்கொள்கிறேன் .

நோயாளிகள் ஒப்புதல்

இந்த நோய், அதற்கான பரிசோதனை மற்றும் நடத்தப்படும் ஆய்வை பற்றி
முழுமையாக மருத்துவர் விளக்கினார். நான் இந்த ஆய்வில் பங்கெடுக்க முழு
மனதுடன் சம்மதம் தெரிவிக்கின்றேன் .

நோயாளியின் கையொப்பம்

அனுப்புனர்

பெயர் :
தந்தை பெயர் :
முகவரி :
வயது :

பெறுநர்

ஐயா,

நான் மேற்சொன்ன முகவரியில் வசித்து வருகிறேன்.தற்போது தொழில் செய்து வருகிறேன். எனக்கு சிறுநீர் கழிப்பதில் சிரமம், அடைப்பு, அடிக்கடி கழித்தல் போன்ற தொந்தரவிற்காக ஸ்டான்லி மருத்துவமனை வந்துள்ளேன். என்னை பரிசோதித்த மருத்துவர் எனக்கு சிறுநீர் வரும் பாதையில் அடைப்பு உள்ளதாகவும் அதற்கு ஆபரேஷன் செய்ய வேண்டிய அவசியத்தை விளக்கிக் கூறினார். இந்த நோயை பற்றிய சந்தேகங்களை நான் கேட்க விளக்கினார் .இந்த ஆபரேஷன் தன்மை,பக்க மற்றும் பின் விளைவுகளையும் மருத்துவர் விளக்கினார்.

. இந்த இந்த ஆய்வினால் எனக்கும் பொதுவாக சிறுநீர் கழிக்கும் பாதையில் அடைப்பு உள்ளவர்களுக்கும் கூடிய நன்மைகள் எனக்கு எடுத்துரைக்கப்பட்டன. இந்த ஆய்வு குறித்து, நான் எழுப்பிய வினாக்கள் மற்றும் சந்தேகங்களுக்கு மருத்துவர் விளக்கமாக பதிலளித்தார். இவற்றை தெரிந்து கொண்ட நான் எனது சுய நினைவுடன் இந்த ஆய்வில் பங்கேற்க எனது விருப்பத்தின்பேரில் யாருடைய நிர்பந்தமும் இல்லாமல் என் சுய நினைவுடன் இந்த ஆய்வில் பங்கேற்க எனது விருப்பத்தை தெரிவித்துக்கொள்கிறேன். இந்த ஆய்வு, என்னுடைய, மற்றும் என் போன்ற நோயாளியர் நலன் கருதியே செய்யப்படுகிறது என்பதை அறிந்ததால் இதற்கு என்னை ஆட்படதுகின்றேன்.

இந்த ஆய்வு குறித்து முழு விவரங்களை நான் கேட்டு பெற்றுள்ளதாலும், என்னுடைய விருப்பத்தின்பேரில் பங்கு கொள்வதாலும், இது குறித்து எந்த குற்ற முறையீட்டையும் மருத்துவர் மீதோ, ஏனைய மருத்துவ ஊழியர்கள் மீதோ, மருத்துவமனை மீதோ எந்த நிலையிலும் வைக்க மாட்டேன். இதையே என்னுடைய ஒப்புதல் மற்றும் வேண்டுகோள் கடிதமாக ஏற்றுக்கொள்ளுமாறு கேட்டுக்கொள்கிறேன்.

நோயாளியின் கையொப்பம்

சிறுநீர் பாதையில் ஏற்படும் அடைப்பிற்கு அறுவை சிகிச்சையின் பொதுத் த்ரியாம்சினலோன் என்னும் மருந்தினை செலுத்துவதால் ஏற்படும் விளைவுகள் பற்றிய ஆய்வு .

நோயாளியின் ஒப்புதல் படிவம்

ஆராய்ச்சி நிலையம் : அரசு ஸ்டான்லி மருத்துவமனை, சென்னை 600001

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் கையொப்பம் :

பங்கு பெறுபவர் இதனை () குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது .

☐

நான் இந்த ஆய்வில் தன்னிச்சையாகத்தான் பங்குபெருகிறேன் .எந்த காரணத்தினாலோ எந்த சட்ட சிக்கல்களுக்கும் உட்படாமல் நான் இந்த ஆய்வில் இருந்து விலகிக்கொள்ளலாம் என்று அறிந்து கொண்டேன்.

☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்துகொள்கிறேன்.நான் ஆய்வில் இருந்து விலகிக்கொண்டாலும் இது பொருந்தும் என அறிந்தேன்.

☐

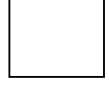
இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் , பரிசோதனை முடிவுகளையும், மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட
அறிவுரைகளின் படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும்
மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதி
அளிகின்றேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத,
வழக்திர்க்குமாறன நோய்க்குறி தென்பட்டாலோ உடனே அதை
மருத்துவ அணிக்கு தெருவிப்பேன் என உறுதி அளிக்கிறேன்.



இந்த ஆய்வில் எனக்கு ரத்தம், சிறுநீர், எக்ஸ்ரே, ஸ்கேன், உட்பட
அனைத்து பரிசோதனைகளையும் செய்து கொள்ள நான் முழு
மனதுடன் சம்மதிக்கிறேன்.



பங்கேற்பவரின் கையொப்பம்.....இடம்.....தேதி

கட்டைவிரல் ரேகை.....

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

.....

ஆய்வாளரின் கையொப்பம்.....இடம்.....
தேதி.....

ஆய்வாளரின் பெயர்

S.NO	NAME	AGE	IP NO	SITE OF STRUCTURE	LENGTH OF STRUCT. (cm)	ETIOLOGY	GROUP	PROCEDURE	PRE-OP URINE CULTURE	POST-OP URINE CULTURE	URIC QUANTRO P (mg/d)	NAME CATHETER	3MONTHS	6MONTHS	12MONTHS	RECURRENT
1	Ibrahim	33	224831	bulbar	0.5	trauma	c	IU	NG	NG	pf 6.mt 4.mt.vv 150ml	PF-20ML.MF- 15ml.vv170ml.pv PF-21ML.MF- 160ml.pvc-10ml	pf 3.mt.mt- 15ml.vv170ml.pv PF-21ML.MF- 200ml.pvc-5ml	pf 13.mt.mt- 14ml.vv-20ml pf-5ml	pf 13.mt.mt- 14ml.vv-20ml pf-5ml	NO
2	ajayendran	53	21185	bulbar	1	idiopathic	c	IU	NG	NG	pf 9.mt.mt-4.mt.vv 150ml	PF-21ML.MF- 14ml.vv160ml.pv PF-10ml	pf 10.mt.mt- 14ml.vv-200ml.pv PF-20ml.mt- 50ml			yes,6 months
3	anandan	53	21200	penile urethra,	1	inflamm	c	IU	NG	E-coli	pf 5.6.mt.mt 2.7.mt.vv-360ml	PF-23ML.MF- 10ml.vv300ml.pv PF-28ML.MF- 150ml	pf 10.mt.mt pf-22ml.mt- 15ml.vv- PF-22ml.mt- 15ml.vv- 200ml.pvc-4ml	best follow up		
4	janakiraman	30	319531	Penile	1	idiopathic	c	IU	E-coli	NG	PF-6.mt.mt- 2.mt.vv-180ml	pf 42.mt.mt- 12.5ml.vv210ml. pvc-10ml	pf 42.mt.mt- 15ml.vv- PF-22ml.mt- 15ml.vv- 200ml.pvc-4ml	best follow up		No
5	babu	45	32064	bulbar urethra	1.5	idiopathic	c	IU	NG	pseudomonas	pf 6.mt.mt 3.mt.vv 150ml	PF-18ml.MF- 13.mt.vv200ml PF-22ML.MF- 150ml.pvc-10ml	pf 9.mt.mt 6.mt.vv PF-17ML.MF- 145ml			yes,3months
6	salem	41	40977	bulbar urethra	1	trauma	c	IU	NG	NG	spc	10ml.vv- 160ml.pvc-10ml	PF-22ML.MF- 14ml.vv160ml.pv PF-10ml	pf 15ml.mt- 12ml.vv-210ml		NO
7	purushothaman	26	50396	bulbar urethra	1.2	trauma	c	IU	pseudomonas	NG	spc	PF-22ML.MF- 10.5ml.vv300ml. pvc-10ml	pf 20ML.MF- 15ml.vv170ml.pv PF-150ml	pf 20ml.mt- 200ml.pvc-5ml PF-150ml	pf 20ml.mt- 15ml.vv180ml.pv pf-10ml- 6ml.vv180ml.pvc- 60ml	yes,6 months
8	prasadss	70	51772	penile	1	inflamm	c	IU	NG	NG	spc	PF-22ml.MF- 9.mt.vv-280ml PF-24ml.MF- 100ml	pf 22ml.mt- pf 22ml.mt- 260ml.pvc-10ml PF-22ml.mt- 260ml.pvc-10ml	pf 21ml.mt- 17ml.vv245ml	pf 20ml.mt- 15ml.vv180ml.pv pf-10ml- 6ml.vv180ml.pvc- 60ml	NO
9	aranganathan	38	53377	bulbar urethra	1	idiopathic	c	IU	E-coli	NG	pf 6.mt.mt- 4.mt.vv152ml.pvc 100ml	PF-24ml.MF- 11ml.vv- 300ml.pvc-nil	pf 42.mt.mt- 18ml.vv-245ml PF-22ml.mt- 18ml.vv-245ml	pf 21ml.mt- 17ml.vv245ml	pf 21ml.mt- 17ml.vv245ml	yes,11months
10	chitbabu	50	52816	prox.penile	1.5	trauma	c	IU	E-coli	NG	pf 6.mt.mt 3.5.mt.vv2-150ml	PF-24ml.MF- 13.mt.vv- 300ml.pvc-5ml PF-24ml.mt- 300ml.pvc-nil	pf 42.mt.mt- 18ml.vv-245ml PF-22ml.mt- 18ml.vv-245ml	pf 10.mt.mt pf-10ml- 320ml.pvc-nil PF-22ml.mt- 15ml.vv250ml PF-22ml.mt- 15ml.vv250ml	pf 10.mt.mt pf-10ml- 320ml.pvc-nil PF-22ml.mt- 15ml.vv250ml PF-22ml.mt- 15ml.vv250ml	yes,10months
11	umeshankar	35	53715	bulbar urethra	1.4	inflamm	c	IU	NG	E-coli	pf 7.mt.mt- 3.mt.vv180ml	PF-24ml.MF- 11ml.vv- 320ml.pvc-nil	pf 42.mt.mt- 230ml.pvc-10ml PF-22ml.mt- 18ml.vv-245ml	pf 16ml.mt- 11ml.vv-240ml	4.mt.vv165ml.pvc- 70ml	yes,3months
12	tharmalingam	47	53374	prox.penile	1	trauma	c	IU	pseudomonas	NG	spc	PF-24ml.MF- 300ml.pvc-nil PF-22ML.MF- 300ml.pvc-nil	pf 42.mt.mt- 18ml.vv-245ml PF-22ML.MF- 15ml.vv-245ml	pf 25ml.mt- 12ml.vv-300ml PF-20ML.MF- 15ml.vv170ml.pv	16.mt.vv220ml.pvc- 12ml.vv300ml PF-20ml.mt- 15ml.vv180ml.pv	NO
13	chithrai	52	8079	bulbar urethra	1	trauma	c	IU	E-coli	E-coli	pf 4.mt.mt 3.mt.vv 150ml.pvc-160ml PF-24ml.MF- 150ml.pvc-5ml	PF-24ml.MF- 10ml.vv- 300ml.pvc-5ml PF-24ml.MF- 150ml.pvc-5ml	pf 4.mt.mt 3.mt.vv 200ml.pvc-5ml PF-24ml.MF- 150ml.pvc-5ml	pf 24ml.mt- 17ml.vv230ml PF-24ml.MF- 150ml.pvc-5ml	pf 4.mt.mt 3.mt.vv 200ml.pvc-5ml PF-24ml.MF- 150ml.pvc-5ml	NO
14	dhil	72	55544	bulbar urethra	1.3	retrogenic	c	IU	NG	pseudomonas	pf 9.mt.mt 4.mt.vv 150ml	PF-24ml.MF- 10ml.vv- 300ml.pvc-5ml PF-24ml.MF- 150ml.pvc-5ml	pf 42.mt.mt- 18ml.vv-245ml PF-22ml.mt- 18ml.vv-245ml	best follow up		yes,9months
15	purnasamy	50	17930	bulbar	1	idiopathic	c	IU	NG	E-coli	pf 9.mt.mt 4.mt.vv 150ml	PF-24ml.MF- 11ml.vv- 320ml.pvc-nil	pf 16ml.mt- 18ml.vv-245ml PF-24ml.MF- 18ml.vv-245ml	pf 21ml.mt- 17ml.vv245ml PF-24ml.MF- 18ml.vv-245ml	pf 22ml.mt- 16ml.vv220ml.pv PF-10ml	yes,9months
16	jantharasan	52	22989	bulbar	0.5	trauma	c	IU	E-coli	NG	pf 7.mt.mt- 3.mt.vv180ml	PF-24ml.MF- 11ml.vv- 320ml.pvc-nil	pf 42.mt.mt- 18ml.vv-245ml PF-24ml.MF- 18ml.vv-245ml	pf 21ml.mt- 17ml.vv245ml PF-24ml.MF- 18ml.vv-245ml	pf 22ml.mt- 16ml.vv220ml.pv PF-10ml	NO
17	sakar	40	26021	bulbar	1.8	trauma	c	IU	NG	pseudomonas	pf 5.6.mt.mt 2.7.mt.vv-360ml	PF-18ml.MF- 13.mt.vv200ml PF-22ML.MF- 150ml.pvc-10ml	pf 16ml.mt- 18ml.vv-245ml PF-22ML.MF- 150ml.pvc-10ml	pf 16ml.mt- 18ml.vv-245ml PF-22ML.MF- 150ml.pvc-10ml	PF-13ML.MF- 9ML.VV270ML.P PF-19ML.MF- 15ML.VV-20ml	yes,6months
18	munusamy	40	26565	bulbar	1.5	idiopathic	c	IU	NG	E-coli	spc	PF-20ML.MF- 13.4.mt.vv- 230ml.pvc-5ml	PF-20ML.MF- 13.4.mt.vv- 230ml.pvc-5ml	PF-20ML.MF- 13.4.mt.vv- 230ml.pvc-5ml	PF-20ML.MF- 13.4.mt.vv- 230ml.pvc-5ml	yes,9months
19	parameswaram	65	28435	bulbar	1	idiopathic	c	IU	pseudomonas	NG	pf 4.mt.mt 3.mt.vv 150ml.pvc-160ml	PF-23ml.MF- 17ml.vv300ml.pv PF-20ML.MF- 15ml.vv170ml.pv PF-10ml	PF-23ml.MF- 17ml.vv300ml.pv PF-20ML.MF- 15ml.vv170ml.pv PF-10ml	PF-23ml.MF- 17ml.vv300ml.pv PF-20ML.MF- 15ml.vv170ml.pv PF-10ml	PF-23ml.MF- 17ml.vv300ml.pv PF-20ML.MF- 15ml.vv170ml.pv PF-10ml	NO
20	rosario	51	2935	prox.penile	1	trauma	c	IU	NG	pseudomonas	pf 4.mt.mt 3.mt.vv 2.mt.vv-210ml	PF-23ml.MF- 11ML.VV- 17ml.vv245ml PF-19ML.MF- 15ML.VV-20ml	PF-23ml.MF- 11ML.VV- 17ml.vv245ml PF-19ML.MF- 15ML.VV-20ml	PF-23ml.MF- 11ML.VV- 17ml.vv245ml PF-19ML.MF- 15ML.VV-20ml	PF-23ml.MF- 11ML.VV- 17ml.vv245ml PF-19ML.MF- 15ML.VV-20ml	NO
21	David	60	3917	bulbar	1.5	trauma	c	IU	proteus	NG	spc	PF-19ML.MF- 14ML.VV-200ML	PF-19ML.MF- 14ML.VV-200ML	PF-19ML.MF- 14ML.VV-200ML	PF-19ML.MF- 14ML.VV-200ML	yes,6months
22	neelanjothi	33	5711	bulbar	1.2	trauma	c	IU	NG	NG	PF-10ML.MF- 6ML.VV-170ML PF-21ML.MF- 17ML.VV-165ML	PF-21ML.MF- 14ml.vv160ml.pv PF-10ml	PF-21ML.MF- 14ml.vv160ml.pv PF-10ml	PF-21ML.MF- 14ml.vv160ml.pv PF-10ml	PF-21ML.MF- 14ml.vv160ml.pv PF-10ml	NO
23	Sivalingam	40	6211	bulbar	1	unknown	c	IU	NG	E-coli	pf 6.mt.mt- 4.mt.vv152ml.pvc 100ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	yes,
24	Ravi	40	7064	bulbar	1.2	retrogenic	c	IU	E-coli	NG	pf 8.mt.mt 4.mt.vv 150ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	NO
25	sathish kumar	26	26140	bulbar	1	inflamm	c	IU+Ttammn	NG	NG	pf 4.7.mt.MF- 2.2ML.VV-240	PF-23ML.MF- 23.9ML.9.6ML.25 OML	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	PF-23ML.MF- 14ml.vv160ml.pv PF-10ml	NO

26	Parthiban	28	32948	bulbar	1	trauma	D	ILU+Ttarsch	proteus	NG	spc	PF-230L,MF-120L,vv-210ML	PF-200L,MF-140L,vv-160ml,pv-100ml,vv-200ml,pv-60ml	PF-190L,MF-150L,vv-220ML,PvR-40L	NO	
27	santhakan	25	34652	Bulbar	0.8	trauma	D	ILU+Ttarsch	NG	NG	spc	PF-240L,MF-120L,vv-175ML	PF-240L,MF-90L,vv-230ml,pv-5ml	PF-240L,MF-100L,vv-200ml,pv-5ml	NO	
28	rajasekar	53	34890	mid penile urethra	1.1	kilopathic	D	ILU+Ttarsch	NG	E-coil	spc	PF-200L,MF-100L,vv-180ML	PF-200L,MF-90L,vv-230ml,pv-5ml	PF-80L,MF-40L,vv-180ML	yes,9months	
29	Viduthan	65	46586	bulbar	1.3	trauma	D	ILU+Ttarsch	NG	NG	PF-40L,MF-250L,vv-180ML,PvR-180ML	PF-210L,MF-100L,vv-190ML	PF-180L,MF-90L,vv-130L,vv-230ML,PvR-50ML	PF-190L,MF-150L,vv-230ML,PvR-40L	NO	
30	Saravappa	53	44026	bulbar	1	infram	D	ILU+Ttarsch	pseudomonas	NG	PF-100L,MF-60L,vv-170ML	PF-240L,MF-120L,vv-175ML	PF-230L,MF-120L,vv-234ml	PF-200L,MF-920L,vv-190ML	no	
31	smali	55	7732	bulbar	1.2	kilopathic	D	ILU+Ttarsch	E-coil	NG	PF-60L,MF-150ml	PF-200L,MF-140L,vv-200ML	PF-180L,MF-80L,vv-230ML,PvR-230ML,PvR-90L,vv-110ml	PF-160L,MF-950L,vv-210ML,Pv-70ml	yes,11months	
32	Jayaraman	60	8833	bulbar	1	trauma	D	ILU+Ttarsch	NG	NG	PF-100L,MF-60L,vv-170ML	PF-230L,MF-100L,vv-210ML	PF-210L,MF-100L,vv-160ml,pv-110L,vv-230ML	PF-190L,MF-90L,vv-230ML,PvR-40L	NO	
33	dhanalingam	47	9386	mid penile	0.5	ultragonic	D	ILU+Ttarsch	NG	NG	PF-60L,MF-150ml	PF-250L,MF-90L,vv-170ml	PF-230L,MF-110L,vv-245ml,pv-110L,vv-230ML	PF-200L,MF-90L,vv-200ml,pv-5ml	NO	
34	panthyan	45	9418	bulbar	1	kilopathic	D	ILU+Ttarsch	NG	NG	PF-60L,MF-150ml	PF-220L,MF-100L,vv-200ml	PF-210L,MF-90L,vv-190ml	PF-180L,MF-100L,vv-200ml	NO	
35	sewaraj	40	9796	bulbar	1.2	trauma	D	ILU+Ttarsch	E-coil	NG	spc	PF-190L,MF-80L,vv-200ML	PF-190L,MF-80L,vv-170ml,pv-90L,vv-230ML	PF-180L,MF-90L,vv-180ml	NO	
36	kumar	43	12333	bulbar	1.5	infram	D	ILU+Ttarsch	NG	NG	PF-50L,MF-320L,vv-160ml,pv-100ml	PF-210L,MF-100L,vv-240ml	PF-215L,MF-90L,vv-200ml,pv-5ml	PF-210L,MF-90L,vv-200ml,pv-5ml	NO	
37	arunugan	47	12399	bulbar	0.8	kilopathic	D	ILU+Ttarsch	NG	E-coil	PF-100L,MF-60L,vv-170ML	PF-240L,MF-90L,vv-210ml	PF-230L,MF-90L,vv-230ml	PF-230L,MF-90L,vv-230ml	NO	
38	kumar	32	16280	bulbar	1.5	kilopathic	D	ILU+Ttarsch	NG	pseudomonas	spc	PF-55L,MF-420L,vv-160ml,pv-80ml	PF-245L,MF-120L,vv-200ml	PF-215L,MF-100L,vv-230ml,pv-5ml	PF-215L,MF-100L,vv-230ml,pv-5ml	yes, 10 months
39	santharam	24	16656	bulbar	1.3	trauma	D	ILU+Ttarsch	NG	NG	PF-55L,MF-420L,vv-160ml,pv-80ml	PF-245L,MF-120L,vv-200ml	PF-215L,MF-100L,vv-230ml,pv-5ml	PF-215L,MF-100L,vv-230ml,pv-5ml	NO	
40	senithikumar	37	17023	bulbar	1	infram	D	ILU+Ttarsch	NG	NG	PF-70L,MF-30L,vv-180ml	PF-215L,MF-100L,vv-230ml,pv-5ml	PF-215L,MF-100L,vv-230ml,pv-5ml	PF-215L,MF-100L,vv-230ml,pv-5ml	NO	
41	karunhan	38	17743	bulbar	0.9	trauma	D	ILU+Ttarsch	Klebsiella	NG	PF-50L,MF-160ml,pv-90ml	PF-230L,MF-90L,vv-250ml	PF-230L,MF-90L,vv-250ml	PF-230L,MF-90L,vv-250ml	NO	
42	anulraj	48	20804	mid penile	1.5	infram	D	ILU+Ttarsch	NG	NG	not voided	PF-270L,MF-100L,vv-200ml	PF-270L,MF-100L,vv-200ml	PF-270L,MF-100L,vv-200ml	NO	
43	karthikan	23	19567	bulbar	1	kilopathic	D	ILU+Ttarsch	E-coil	NG	PF-50L,MF-320L,vv-160ml,pv-80ml	PF-245L,MF-120L,vv-200ml	PF-215L,MF-100L,vv-230ml,pv-5ml	PF-215L,MF-100L,vv-230ml,pv-5ml	yes, 10months	
44	subashin	43	2186	bulbar	1.2	trauma	D	ILU+Ttarsch	NG	E-coil	PF-90L,MF-150ml	PF-240L,MF-120L,vv-175ML	PF-230L,MF-120L,vv-234ml	PF-200L,MF-920L,vv-190ML	NO	
45	appanraj	33	26553	penile	0.9	kilopathic	D	ILU+Ttarsch	NG	NG	PF-70L,MF-30L,vv-180ml	PF-240L,MF-120L,vv-175ML	PF-230L,MF-120L,vv-234ml	PF-200L,MF-920L,vv-190ML	NO	
46	ethunah	27	28752	bulbar	1	trauma	D	ILU+Ttarsch	NG	NG	PF-40L,MF-150ml	PF-240L,MF-120L,vv-175ML	PF-230L,MF-120L,vv-234ml	PF-200L,MF-920L,vv-190ML	NO	
47	kasi	35	24007	bulbar	0.7	infram	D	ILU+Ttarsch	NG	NG	spc	PF-220L,MF-90L,vv-232ml	PF-220L,MF-90L,vv-232ml	PF-220L,MF-90L,vv-232ml	NO	
48	Parthiban	28	28007	bulbar	1	kilopathic	D	ILU+Ttarsch	E-coil	NG	PF-50L,MF-175L,pv-100ml	PF-240L,MF-90L,vv-180	PF-240L,MF-90L,vv-180	PF-240L,MF-90L,vv-180	NO	
49	gillishabu	49	26290	bulbar	0.5	trauma	D	ILU+Ttarsch	NG	NG	PF-60L,MF-150ml	PF-240L,MF-120L,vv-175ML	PF-230L,MF-120L,vv-234ml	PF-200L,MF-920L,vv-190ML	NO	
50	saravanan	48	32064	bulbar	1.2	kilopathic	D	ILU+Ttarsch	NG	E-coil	PF-60L,MF-150ml	PF-240L,MF-120L,vv-175ML	PF-230L,MF-120L,vv-234ml	PF-200L,MF-920L,vv-190ML	yes,9months	